

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-165/S-020

Name: Nicoderm CQ (Nicotine Transdermal System)
Clear and Opaque, 7 mg, 14 mg, and 7 mg

Sponsor: GlaxoSmithKline Consumer Healthcare

Approval Date: August 13, 2002

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
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APPLICATION NUMBER:

NDA 20-165/S-020

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN
SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-165/S-020

GlaxoSmithKline Consumer Healthcare
Attention: Mr. Parker J. Holmes
Manager, Regulatory Affairs
1500 Littleton Road,
Parsippany, N.J 07054-3884

Dear Mr. Holmes:

Please refer to your supplemental new drug application dated February 13, 2002, received February 14, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NicoDerm CQ (nicotine transdermal system) clear and opaque, 21mg, 14mg, and 7 mg.

Your submission of February 13, 2002, constituted a complete response to our August 17, 2001 letter.

This Changes Being Effected in 30 days supplemental new drug application provides for revised labeling, replacing the current pregnancy warning with the following:

If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

In addition, we note the three minor editorial changes have been made to the user's guide labeling which involve a change in the location of the text.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (user's guide and carton labels submitted February 13, 2002), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL for all Stock Keeping Units (SKUs) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-165/S-020." Approval of this submission by FDA is not required before the labeling is used.

In addition, please note the following minor editorial revision should be made at the next printing and noted in the following annual report:

- On the end flap of all the cartons an apostrophe should be inserted in the word "family's" in the sentence "For your family's protection, NicoDerm CQ patches are supplied in child resistant pouches."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Elaine Abraham, Regulatory Project Manager, at (301) 827-2301.

Sincerely,

{See appended electronic signature page}

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over the Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Linda Katz

8/13/02 08:20:00 AM

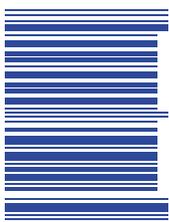
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-165/S-020

LABELING

VARNISH/KO
50065352
50065352
50065352

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CQ
STEP 1
21 mg

CQ
STEP 2
14 mg

CQ
STEP 3
7 mg

FREE
Personalized
STOP SMOKING PLAN
DETAILS
INSIDE

3 STEP PROGRAM
NicoDerm CQ is a three step program. You start with the highest level of medicine and gradually step down your dose.
If you smoke 10 or less cigarettes per day, start with Step 2.

VARNISH/KO
50065352

American Cancer Society
See Side Panel*



TIPS
TO HELP MAKE
QUITTING EASIER

CLEAR
NICODERM
NICOTINE TRANSDERMAL SYSTEM
21 mg DELIVERED OVER 24 HOURS
STOP SMOKING AID
CQ

If You Smoke:
• more than 10 cigarettes per day: start with Step 1
• 10 or less cigarettes per day: start with Step 2

STEP 1
2 WEEK KIT

STEP 2

STEP 3

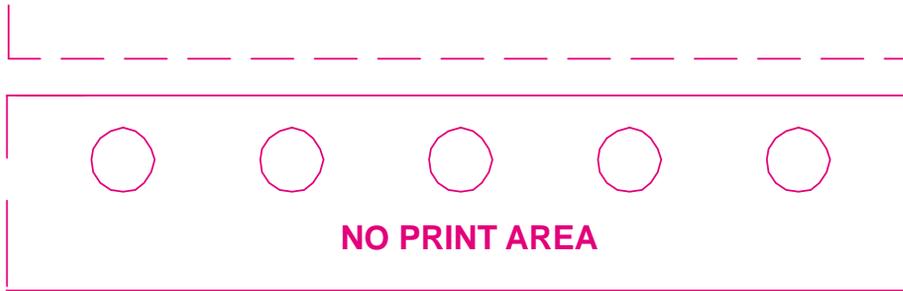
14 PATCHES Committed Quitters® Program enrollment form, user's guide, CD and child resistant disposal tray.

NICODERM
CQ
nicotine transdermal system

What is the NicoDerm CQ Patch and How is it Used?
NicoDerm CQ is a small, nicotine-containing patch. When you put on a NicoDerm CQ patch, nicotine passes through the skin and into your body. NicoDerm CQ is very thin and uses special material to control how fast nicotine passes through the skin. Unlike the sudden jolts of nicotine delivered by cigarettes, the amount of nicotine you receive remains relatively smooth throughout the 24 or 16 hour period you wear the NicoDerm CQ patch. This helps to reduce cravings you may have for nicotine.

NicoDerm Clear Step 1, 14 Count Front and Top Flaps

<p>Drug Facts</p> <p>Active ingredient (in each patch) Nicotine, 21 mg delivered over 24 hours.....Purpose Stop smoking aid</p> <p>Use reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking</p> <p>Warnings If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.</p> <p>Do not use • if you continue to smoke, chew tobacco, use snuff, or use a nicotine gum or other nicotine containing products</p> <p>Ask a doctor before use if you have • heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate. • high blood pressure not controlled with medication. Nicotine can increase your blood pressure. • an allergy to adhesive tape or have skin problems because you are more likely to get rashes</p> <p>Ask a doctor or pharmacist before use if you are • using a non-nicotine stop smoking drug • taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.</p> <p>When using this product • do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your blood stream for several hours after you take off the patch. • if you have vivid dreams or other sleep disturbances remove this patch at bedtime</p> <p>Stop use and ask a doctor if • skin redness caused by the patch does not go away after four days, or if your skin swells, or you get a rash • irregular heartbeat or palpitations occur • you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, weakness and rapid heartbeat</p> <p>Keep out of reach of children and pets. Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Dispose of the used patches by folding sticky ends together and inserting in disposal tray in this box.</p>		<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> if you are under 18 years of age, ask a doctor before use before using this product, read the enclosed user's guide for complete directions and other information stop smoking completely when you begin using the patch if you smoke more than 10 cigarettes per day, use according to the following 10 week schedule: <table border="1"> <thead> <tr> <th>STEP 1</th> <th>STEP 2</th> <th>STEP 3</th> </tr> </thead> <tbody> <tr> <td>Use one 21 mg patch/day</td> <td>Use one 14 mg patch/day</td> <td>Use one 7 mg patch/day</td> </tr> <tr> <td>Weeks 1-6</td> <td>Weeks 7-8</td> <td>Weeks 9-10</td> </tr> </tbody> </table> <ul style="list-style-type: none"> if you smoke 10 or less cigarettes per day, do not use STEP 1 (21 mg). Start with STEP 2 (14 mg) for 6 weeks, then STEP 3 (7 mg) for 2 weeks and then stop. steps 2 and 3 allow you to gradually reduce your level of nicotine. Completing the full program will increase your chances of quitting successfully. apply one new patch every 24 hours on skin that is dry, clean and hairless remove backing from patch and immediately press onto skin. Hold for 10 seconds. wash hands after applying or removing patch. Throw away the patch in the enclosed disposal tray. See enclosed user's guide for safety and handling. you may wear the patch for 16 or 24 hours if you crave cigarettes when you wake up, wear the patch for 24 hours if you have vivid dreams or other sleep disturbances, you may remove the patch at bedtime and apply a new one in the morning the used patch should be removed and a new one applied to a different skin site at the same time each day do not wear more than one patch at a time do not cut patch in half or into smaller pieces do not leave patch on for more than 24 hours because it may irritate your skin and loses strength after 24 hours stop using the patch at the end of 10 weeks. If you started with STEP 2, stop using the patch at the end of 8 weeks. If you still feel the need to use the patch talk to your doctor. <p>Other information store at 20-25°C(68-77°F)</p> <p>Inactive ingredients ethylene vinyl acetate-copolymer, polyisobutylene and high density polyethylene between clear polyester backings</p> <p>Questions or comments? call 1-800-834-5895 weekdays (10:00 a.m. - 4:30 p.m. EST)</p>	STEP 1	STEP 2	STEP 3	Use one 21 mg patch/day	Use one 14 mg patch/day	Use one 7 mg patch/day	Weeks 1-6	Weeks 7-8	Weeks 9-10
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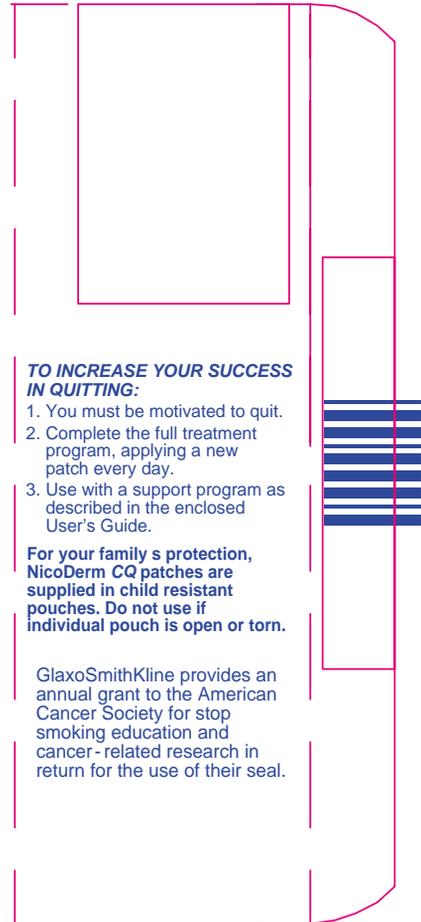
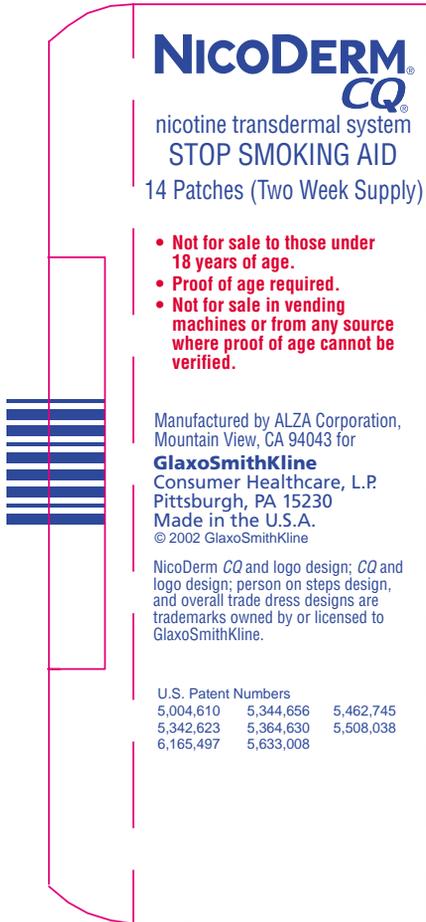
STOP SMOKING AID

READ THE LABEL Read carton and enclosed User's Guide before using this product. Keep the carton and User's Guide. They contain important information.

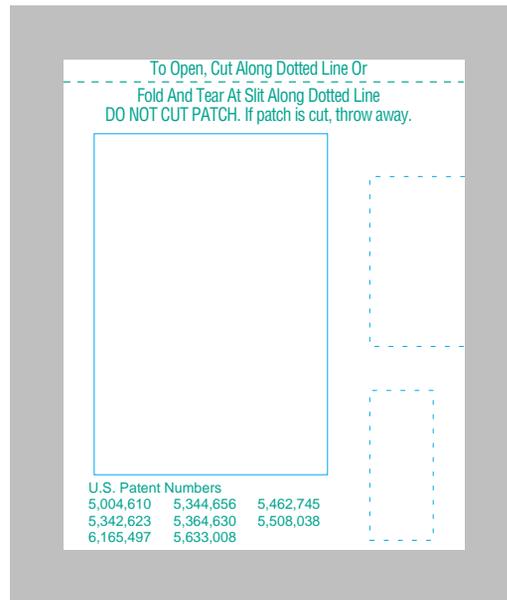
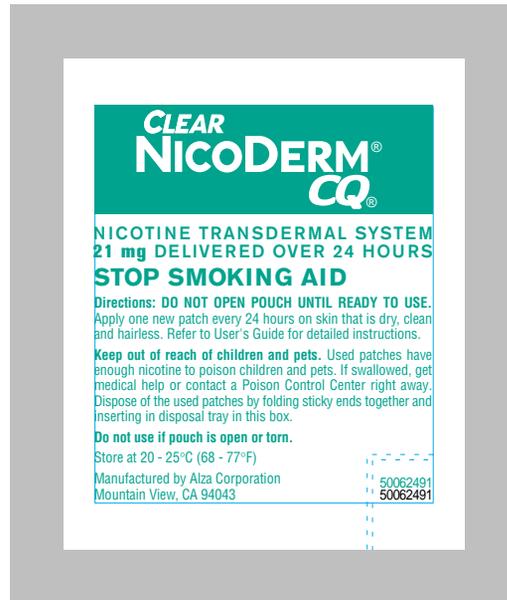
NICODERM CQ
nicotine transdermal system

What is the NicoDerm CQ Patch and How is it Used?
NicoDerm CQ is a small, nicotine-containing patch. When you put on a NicoDerm CQ patch, nicotine passes through the skin and into your body. NicoDerm CQ is very thin and uses special material to control how fast nicotine passes through the skin. Unlike the sudden jolts of nicotine delivered by cigarettes, the amount of nicotine you receive remains relatively smooth throughout the 24 or 16 hour period you wear the NicoDerm CQ patch. This helps to reduce cravings you may have for nicotine.

NicoDerm Clear Step 1, 14 Count Back and Bottom Flaps



NicoDerm Clear Step 1, 14 Count End Flaps



NicoDerm Clear Step 1, Front and Back Pouch



NicoDerm Clear Step 2, 14 Count Front and Top Flaps

<p>Drug Facts</p> <p>Active ingredient (in each patch) Purpose Nicotine, 14 mg delivered over 24 hours..... Stop smoking aid</p> <p>Use reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking</p> <p>Warnings If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.</p> <p>Do not use</p> <ul style="list-style-type: none"> if you continue to smoke, chew tobacco, use snuff, or use a nicotine gum or other nicotine containing products <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate. high blood pressure not controlled with medication. Nicotine can increase your blood pressure. an allergy to adhesive tape or have skin problems because you are more likely to get rashes <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> using a non-nicotine stop smoking drug taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted. <p>When using this product</p> <ul style="list-style-type: none"> do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your blood stream for several hours after you take off the patch. if you have vivid dreams or other sleep disturbances remove this patch at bedtime <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> skin redness caused by the patch does not go away after four days, or if your skin swells, or you get a rash irregular heartbeat or palpitations occur you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, weakness and rapid heartbeat <p>Keep out of reach of children and pets. Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Dispose of the used patches by folding sticky ends together and inserting in disposal tray in this box.</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> if you are under 18 years of age, ask a doctor before use before using this product, read the enclosed user's guide for complete directions and other information stop smoking completely when you begin using the patch if you smoke more than 10 cigarettes per day, use according to the following 10 week schedule: <table border="1"> <thead> <tr> <th>STEP 1</th> <th>STEP 2</th> <th>STEP 3</th> </tr> </thead> <tbody> <tr> <td>Use one 21 mg patch/day</td> <td>Use one 14 mg patch/day</td> <td>Use one 7 mg patch/day</td> </tr> <tr> <td>Weeks 1-6</td> <td>Weeks 7-8</td> <td>Weeks 9-10</td> </tr> </tbody> </table> <ul style="list-style-type: none"> if you smoke 10 or less cigarettes per day, do not use STEP 1 (21 mg). Start with STEP 2 (14 mg) for 6 weeks, then STEP 3 (7 mg) for 2 weeks and then stop. steps 2 and 3 allow you to gradually reduce your level of nicotine. Completing the full program will increase your chances of quitting successfully. apply one new patch every 24 hours on skin that is dry, clean and hairless remove backing from patch and immediately press onto skin. Hold for 10 seconds. wash hands after applying or removing patch. Throw away the patch in the enclosed disposal tray. See enclosed user's guide for safety and handling. you may wear the patch for 16 or 24 hours if you crave cigarettes when you wake up, wear the patch for 24 hours if you have vivid dreams or other sleep disturbances, you may remove the patch at bedtime and apply a new one in the morning the used patch should be removed and a new one applied to a different skin site at the same time each day do not wear more than one patch at a time do not cut patch in half or into smaller pieces do not leave patch on for more than 24 hours because it may irritate your skin and loses strength after 24 hours stop using the patch at the end of 10 weeks. If you started with STEP 2, stop using the patch at the end of 8 weeks. If you still feel the need to use the patch talk to your doctor. <p>Other information store at 20-25°C(68-77°F)</p> <p>Inactive ingredients ethylene vinyl acetate-copolymer, polyisobutylene and high density polyethylene between clear polyester backings</p> <p>Questions or comments? call 1-800-834-5895 weekdays (10:00 a.m. - 4:30 p.m. EST)</p>	STEP 1	STEP 2	STEP 3	Use one 21 mg patch/day	Use one 14 mg patch/day	Use one 7 mg patch/day	Weeks 1-6	Weeks 7-8	Weeks 9-10
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NO PRINT AREA

STOP SMOKING AID



READ THE LABEL

Read carton and enclosed User's Guide before using this product. Keep the carton and User's Guide. They contain important information.

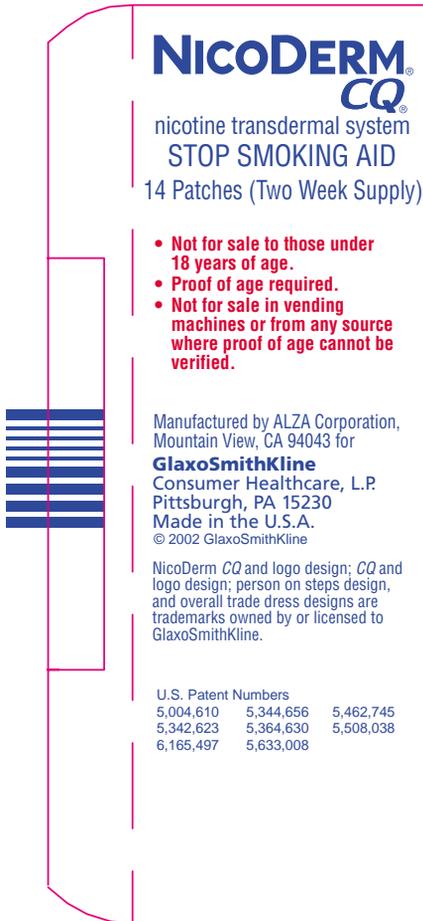
NICODERM CQ

nicotine transdermal system

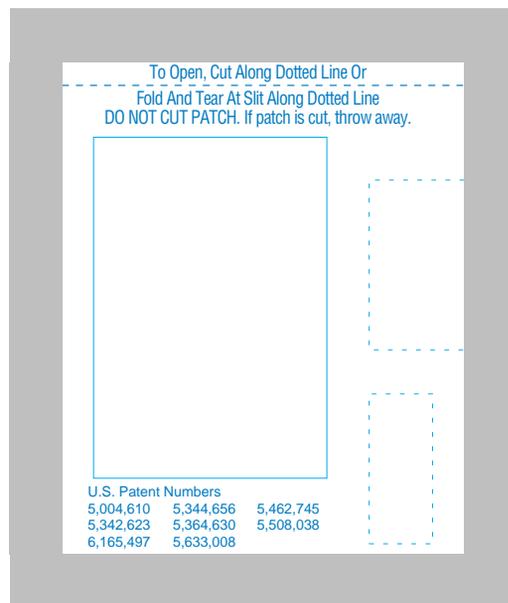
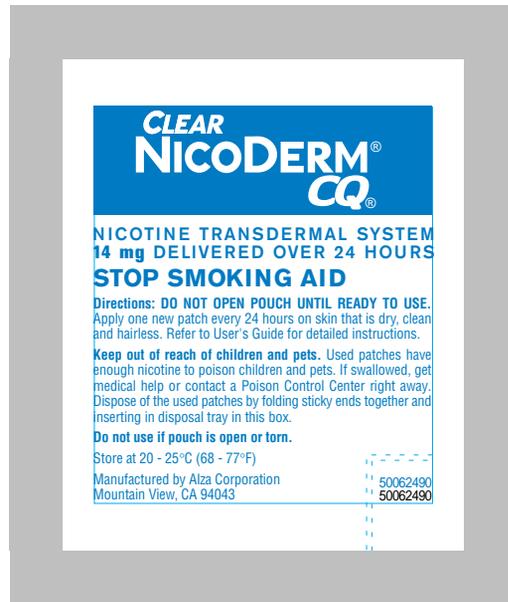
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NicoDerm Clear Step 2, 14 Count Back and Bottom Flaps



NicoDerm Clear Step 2, 14 Count End Flaps



NicoDerm Clear Step 2, Front and Back Pouch



NicoDerm Clear Step 3, 14 Count Front and Top Flaps

<p>Drug Facts</p> <p>Active ingredient (in each patch) Purpose Nicotine, 7 mg delivered over 24 hours..... Stop smoking aid</p> <p>Use reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking</p> <p>Warnings If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.</p> <p>Do not use • if you continue to smoke, chew tobacco, use snuff, or use a nicotine gum or other nicotine containing products</p> <p>Ask a doctor before use if you have • heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate. • high blood pressure not controlled with medication. Nicotine can increase your blood pressure. • an allergy to adhesive tape or have skin problems because you are more likely to get rashes</p> <p>Ask a doctor or pharmacist before use if you are • using a non-nicotine stop smoking drug • taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.</p> <p>When using this product • do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your blood stream for several hours after you take off the patch. • if you have vivid dreams or other sleep disturbances remove this patch at bedtime</p> <p>Stop use and ask a doctor if • skin redness caused by the patch does not go away after four days, or if your skin swells, or you get a rash • irregular heartbeat or palpitations occur • you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, weakness and rapid heartbeat</p> <p>Keep out of reach of children and pets. Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Dispose of the used patches by folding sticky ends together and inserting in disposal tray in this box. ▶</p>	<p>Drug Facts (continued)</p> <p>Directions • if you are under 18 years of age, ask a doctor before use • before using this product, read the enclosed user's guide for complete directions and other information • stop smoking completely when you begin using the patch • if you smoke more than 10 cigarettes per day, use according to the following 10 week schedule:</p> <table border="1"> <thead> <tr> <th>STEP 1</th> <th>STEP 2</th> <th>STEP 3</th> </tr> </thead> <tbody> <tr> <td>Use one 21 mg patch/day</td> <td>Use one 14 mg patch/day</td> <td>Use one 7 mg patch/day</td> </tr> <tr> <td>Weeks 1-6</td> <td>Weeks 7-8</td> <td>Weeks 9-10</td> </tr> </tbody> </table> <p>• if you smoke 10 or less cigarettes per day, do not use STEP 1 (21 mg). Start with STEP 2 (14 mg) for 6 weeks, then STEP 3 (7 mg) for 2 weeks and then stop. • steps 2 and 3 allow you to gradually reduce your level of nicotine. Completing the full program will increase your chances of quitting successfully. • apply one new patch every 24 hours on skin that is dry, clean and hairless • remove backing from patch and immediately press onto skin. Hold for 10 seconds. • wash hands after applying or removing patch. Throw away the patch in the enclosed disposal tray. See enclosed user's guide for safety and handling. • you may wear the patch for 16 or 24 hours • if you crave cigarettes when you wake up, wear the patch for 24 hours • if you have vivid dreams or other sleep disturbances, you may remove the patch at bedtime and apply a new one in the morning • the used patch should be removed and a new one applied to a different skin site at the same time each day • do not wear more than one patch at a time • do not cut patch in half or into smaller pieces • do not leave patch on for more than 24 hours because it may irritate your skin and loses strength after 24 hours • stop using the patch at the end of 10 weeks. If you started with STEP 2, stop using the patch at the end of 8 weeks. If you still feel the need to use the patch talk to your doctor.</p> <p>Other information store at 20-25°C(68-77°F)</p> <p>Inactive ingredients ethylene vinyl acetate-copolymer, polyisobutylene and high density polyethylene between clear polyester backings</p> <p>Questions or comments? call 1-800-834-5895 weekdays (10:00 a.m. - 4:30 p.m. EST)</p>	STEP 1	STEP 2	STEP 3	Use one 21 mg patch/day	Use one 14 mg patch/day	Use one 7 mg patch/day	Weeks 1-6	Weeks 7-8	Weeks 9-10
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STOP SMOKING AID

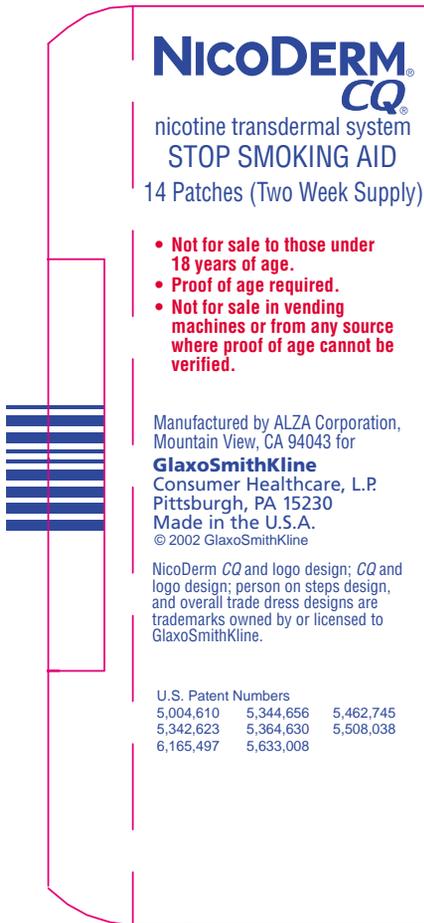
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NICODERM[®]
CQ[®]

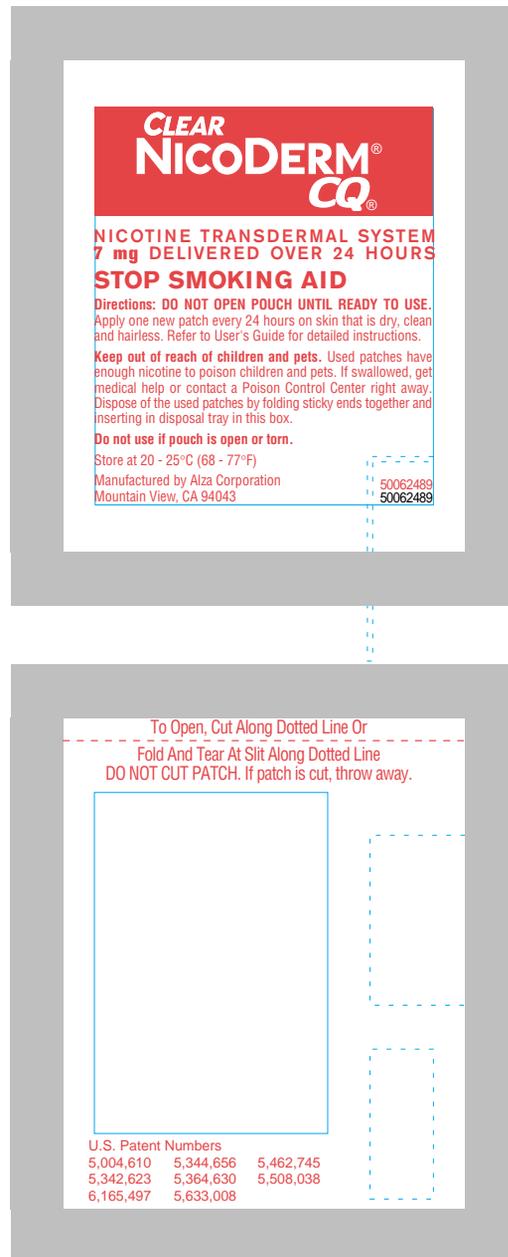
nicotine transdermal system

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NicoDerm Clear Step 3, 14 Count Back and Bottom Flaps



NicoDerm Clear Step 3, 14 Count End Flaps



NicoDerm Clear Step 3, Front and Back Pouch

VARNISH KO
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FREE
enrollment
STOP SMOKING PLAN
DETAILS
INSIDE

3 STEP PROGRAM
NicoDerm CQ is a three step program. You start with the highest level of medicine and gradually step down your dose.
If you smoke 10 or less cigarettes per day, start with Step 2.

CQ
STEP 1
21 mg

CQ
STEP 2
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CQ
STEP 3
7 mg

VARNISH KO
50065343
50065343
50065343

American Cancer Society
See Side Panel*

TIPS
TO HELP MAKE
QUITTING EASIER

NICODERM
NICOTINE TRANSDERMAL SYSTEM
21 mg DELIVERED OVER 24 HOURS
STOP SMOKING AID
CQ

If You Smoke:
• **more than 10 cigarettes per day: start with Step 1**
• 10 or less cigarettes per day: start with Step 2

STEP 1
1 WEEK KIT

STEP 2

STEP 3

7 PATCHES
Committed Quitters® Program enrollment form, user's guide, CD and child resistant disposal tray.

NicoDerm Opaque Step 1, 7 Count Front and Top Flaps

<p>Drug Facts</p> <p>Active ingredient (in each patch) Purpose Nicotine, 21 mg delivered over 24 hours..... Stop smoking aid</p> <p>Use reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking</p> <p>Warnings If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.</p> <p>Do not use</p> <ul style="list-style-type: none"> if you continue to smoke, chew tobacco, use snuff, or use a nicotine gum or other nicotine containing products <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate. high blood pressure not controlled with medication. Nicotine can increase your blood pressure. an allergy to adhesive tape or have skin problems because you are more likely to get rashes <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> using a non-nicotine stop smoking drug taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted. <p>When using this product</p> <ul style="list-style-type: none"> do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your blood stream for several hours after you take off the patch. if you have vivid dreams or other sleep disturbances remove this patch at bedtime <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> skin redness caused by the patch does not go away after four days, or if your skin swells, or you get a rash irregular heartbeat or palpitations occur you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, weakness and rapid heartbeat <p>Keep out of reach of children and pets. Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Dispose of the used patches by folding sticky ends together and inserting in disposal tray in this box.</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> if you are under 18 years of age, ask a doctor before use before using this product, read the enclosed user's guide for complete directions and other information stop smoking completely when you begin using the patch if you smoke more than 10 cigarettes per day, use according to the following 10 week schedule: <table border="1"> <thead> <tr> <th>STEP 1</th> <th>STEP 2</th> <th>STEP 3</th> </tr> </thead> <tbody> <tr> <td>Use one 21 mg patch/day</td> <td>Use one 14 mg patch/day</td> <td>Use one 7 mg patch/day</td> </tr> <tr> <td>Weeks 1-6</td> <td>Weeks 7-8</td> <td>Weeks 9-10</td> </tr> </tbody> </table> <ul style="list-style-type: none"> if you smoke 10 or less cigarettes per day, do not use STEP 1 (21 mg). Start with STEP 2 (14 mg) for 6 weeks, then STEP 3 (7 mg) for 2 weeks and then stop. steps 2 and 3 allow you to gradually reduce your level of nicotine. Completing the full program will increase your chances of quitting successfully. apply one new patch every 24 hours on skin that is dry, clean and hairless remove backing from patch and immediately press onto skin. Hold for 10 seconds. wash hands after applying or removing patch. Throw away the patch in the enclosed disposal tray. See enclosed user's guide for safety and handling. you may wear the patch for 16 or 24 hours if you crave cigarettes when you wake up, wear the patch for 24 hours if you have vivid dreams or other sleep disturbances, you may remove the patch at bedtime and apply a new one in the morning the used patch should be removed and a new one applied to a different skin site at the same time each day do not wear more than one patch at a time do not cut patch in half or into smaller pieces do not leave patch on for more than 24 hours because it may irritate your skin and loses strength after 24 hours stop using the patch at the end of 10 weeks. If you started with STEP 2, stop using the patch at the end of 8 weeks. If you still feel the need to use the patch talk to your doctor. <p>Other information store at 20-25°C(68-77°F)</p> <p>Inactive ingredients ethylene vinyl acetate-copolymer, polyisobutylene and high density polyethylene between pigmented and clear polyester backings</p> <p>Questions or comments? call 1-800-834-5895 weekdays (10:00 a.m. - 4:30 p.m. EST)</p>	STEP 1	STEP 2	STEP 3	Use one 21 mg patch/day	Use one 14 mg patch/day	Use one 7 mg patch/day	Weeks 1-6	Weeks 7-8	Weeks 9-10
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STOP SMOKING AID



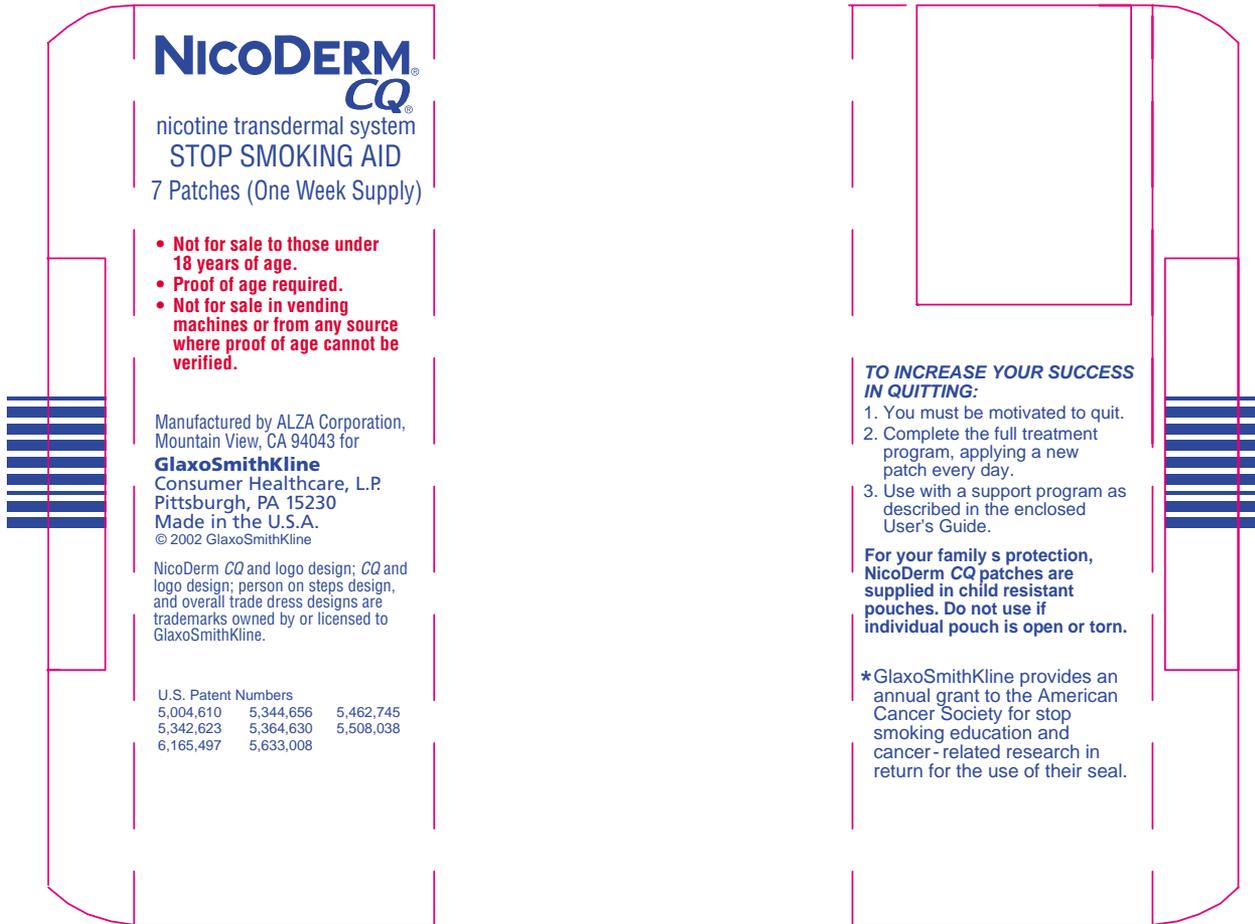
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NICODERM[®]
CQ[®]

nicotine transdermal system

What is the NicoDerm CQ Patch and How is it Used?
NicoDerm CQ is a small, nicotine-containing patch. When you put on a NicoDerm CQ patch, nicotine passes through the skin and into your body. NicoDerm CQ is very thin and uses special material to control how fast nicotine passes through the skin. Unlike the sudden jolts of nicotine delivered by cigarettes, the amount of nicotine you receive remains relatively smooth throughout the 24 or 16 hour period you wear the NicoDerm CQ patch. This helps to reduce cravings you may have for nicotine.

NicoDerm Opaque Step 1, 7 Count Back and Bottom Flaps



NicoDerm Opaque Step 1, 7 Count End Flaps

VARNISH K/O
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50065342

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CQ[®] STEP 1
21 mg

CQ[®] STEP 2
14 mg

CQ[®] STEP 3
7 mg

FREE
Small
STOP SMOKING PLAN[®]
DETAILS
INSIDE

3 STEP PROGRAM
NicoDerm CQ is a three step program. You start with the highest level of medicine and gradually step down your dose.
If you smoke 10 or less cigarettes per day, start with Step 2.

VARNISH K/O
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50065342
50065342

American Cancer Society[®]
See Side Panel*

TIPS
TO HELP MAKE
QUITTING EASIER

NICODERM[®]
NICOTINE TRANSDERMAL SYSTEM
21 mg DELIVERED OVER 24 HOURS
STOP SMOKING AID

CQ[®]

If You Smoke:
• more than 10 cigarettes per day: start with Step 1
• 10 or less cigarettes per day: start with Step 2

STEP 1
2 WEEK KIT

STEP 2

STEP 3

14 PATCHES Committed Quitters[®] Program enrollment form, user's guide, CD and child resistant disposal tray.

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CQ[®]
nicotine transdermal system

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NicoDerm Opaque Step 1, 14 Count Front and Top Flaps

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NO PRINT AREA

STOP SMOKING AID



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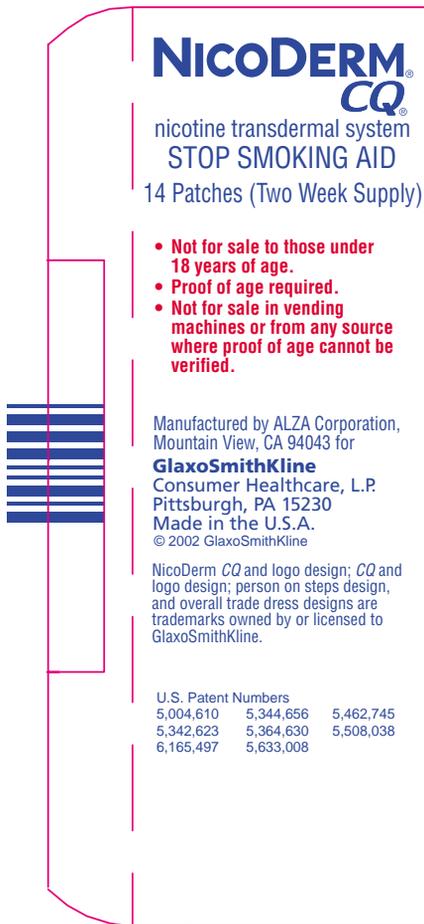
NICODERM[®]
CQ[®]

nicotine transdermal system

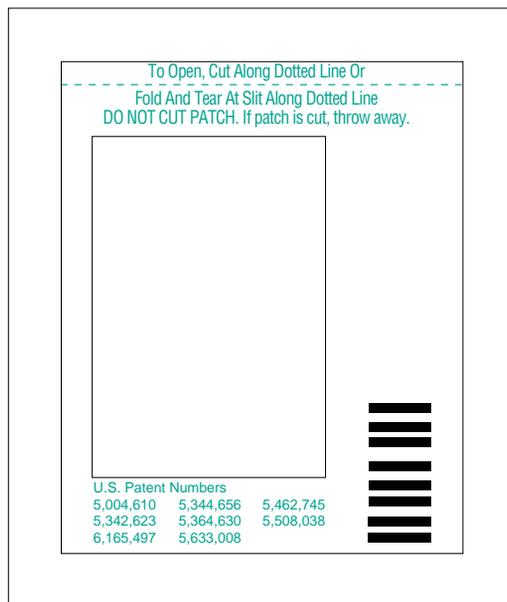
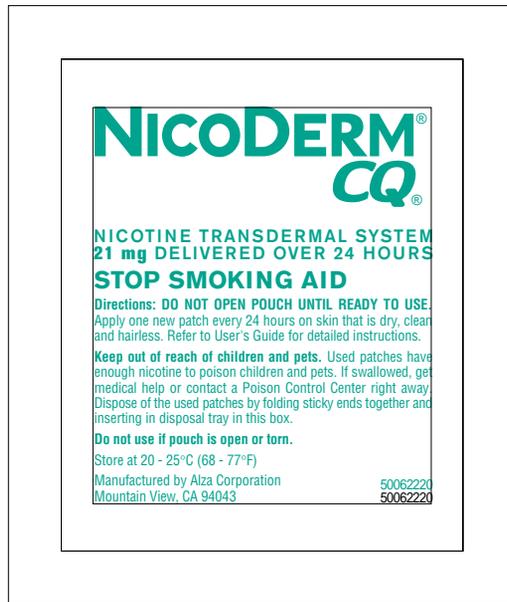
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NicoDerm Opaque Step 1, 14 Count Back and Bottom Flaps



NicoDerm Opaque Step 1, 14 Count End Flaps



NicoDerm Opaque Step 1, Front and Back Pouch

VARNISH KO
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50065344
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3 0766-1460-20 5

FREE
Enrollment
STOP SMOKING PLAN
DETAILS
INSIDE

3 STEP PROGRAM
NicoDerm CQ is a three step program. You start with the highest level of medicine and gradually step down your dose.
If you smoke 10 or less cigarettes per day, start with Step 2.

CQ
STEP 1
21 mg

CQ
STEP 2
14 mg

CQ
STEP 3
7 mg

VARNISH KO
50065344
50065344
50065344

 American Cancer Society®
See Side Panel*

 **TIPS**
TO HELP MAKE
QUITTING EASIER


NICODERM
NICOTINE TRANSDERMAL SYSTEM
14 mg DELIVERED OVER 24 HOURS
STOP SMOKING AID
CQ

If You Smoke:
• more than 10 cigarettes per day: use after completing Step 1
• 10 or less cigarettes per day: start with Step 2

STEP 1

STEP 2
2 WEEK KIT

STEP 3

14 PATCHES Committed Quitters® Program enrollment form, user's guide, CD and child resistant disposal tray.

NICODERM
CQ

nicotine transdermal system

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NicoDerm Opaque Step 2, 14 Count Front and Top Flaps

<p>Drug Facts</p> <p>Active ingredient (in each patch) Nicotine, 14 mg delivered over 24 hours.....</p> <p>Purpose Stop smoking aid</p> <p>Use reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking</p> <p>Warnings If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.</p> <p>Do not use • if you continue to smoke, chew tobacco, use snuff, or use a nicotine gum or other nicotine containing products</p> <p>Ask a doctor before use if you have • heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate. • high blood pressure not controlled with medication. Nicotine can increase your blood pressure. • an allergy to adhesive tape or have skin problems because you are more likely to get rashes</p> <p>Ask a doctor or pharmacist before use if you are • using a non-nicotine stop smoking drug • taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.</p> <p>When using this product • do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your blood stream for several hours after you take off the patch. • if you have vivid dreams or other sleep disturbances remove this patch at bedtime</p> <p>Stop use and ask a doctor if • skin redness caused by the patch does not go away after four days, or if your skin swells, or you get a rash • irregular heartbeat or palpitations occur • you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, weakness and rapid heartbeat</p> <p>Keep out of reach of children and pets. Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Dispose of the used patches by folding sticky ends together and inserting in disposal tray in this box.</p>	<p>Drug Facts (continued)</p> <p>Directions • if you are under 18 years of age, ask a doctor before use before using this product, read the enclosed user's guide for complete directions and other information • stop smoking completely when you begin using the patch • if you smoke more than 10 cigarettes per day, use according to the following 10 week schedule:</p> <table border="1"> <tr> <td style="background-color: #90EE90;">STEP 1</td> <td style="background-color: #4682B4;">STEP 2</td> <td style="background-color: #DC143C;">STEP 3</td> </tr> <tr> <td style="background-color: #90EE90;">Use one 21 mg patch/day</td> <td style="background-color: #4682B4;">Use one 14 mg patch/day</td> <td style="background-color: #DC143C;">Use one 7 mg patch/day</td> </tr> <tr> <td style="background-color: #90EE90;">Weeks 1-6</td> <td style="background-color: #4682B4;">Weeks 7-8</td> <td style="background-color: #DC143C;">Weeks 9-10</td> </tr> </table> <p>• if you smoke 10 or less cigarettes per day, do not use STEP 1 (21 mg). Start with STEP 2 (14 mg) for 6 weeks, then STEP 3 (7 mg) for 2 weeks and then stop. • steps 2 and 3 allow you to gradually reduce your level of nicotine. Completing the full program will increase your chances of quitting successfully. • apply one new patch every 24 hours on skin that is dry, clean and hairless • remove backing from patch and immediately press onto skin. Hold for 10 seconds. • wash hands after applying or removing patch. Throw away the patch in the enclosed disposal tray. See enclosed user's guide for safety and handling. • you may wear the patch for 16 or 24 hours • if you crave cigarettes when you wake up, wear the patch for 24 hours • if you have vivid dreams or other sleep disturbances, you may remove the patch at bedtime and apply a new one in the morning • the used patch should be removed and a new one applied to a different skin site at the same time each day • do not wear more than one patch at a time • do not cut patch in half or into smaller pieces • do not leave patch on for more than 24 hours because it may irritate your skin and loses strength after 24 hours • stop using the patch at the end of 10 weeks. If you started with STEP 2, stop using the patch at the end of 8 weeks. If you still feel the need to use the patch talk to your doctor.</p> <p>Other information store at 20-25°C(68-77°F)</p> <p>Inactive ingredients ethylene vinyl acetate-copolymer, polyisobutylene and high density polyethylene between pigmented and clear polyester backings</p> <p>Questions or comments? call 1-800-834-5895 weekdays (10:00 a.m. - 4:30 p.m. EST)</p>	STEP 1	STEP 2	STEP 3	Use one 21 mg patch/day	Use one 14 mg patch/day	Use one 7 mg patch/day	Weeks 1-6	Weeks 7-8	Weeks 9-10
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NO PRINT AREA

STOP SMOKING AID



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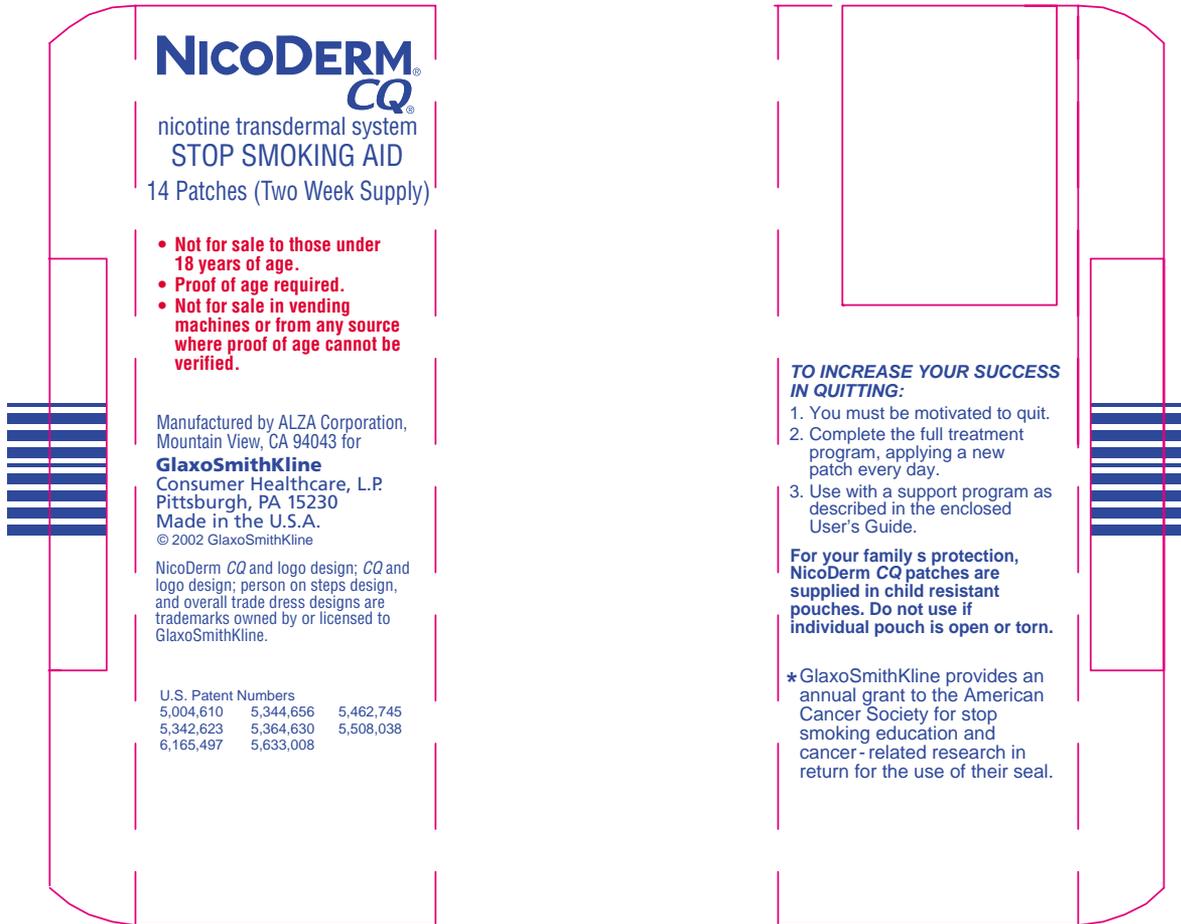
NICODERM CQ

nicotine transdermal system

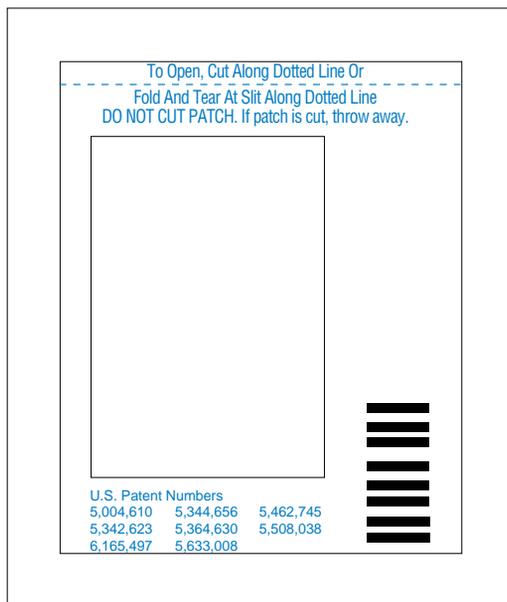
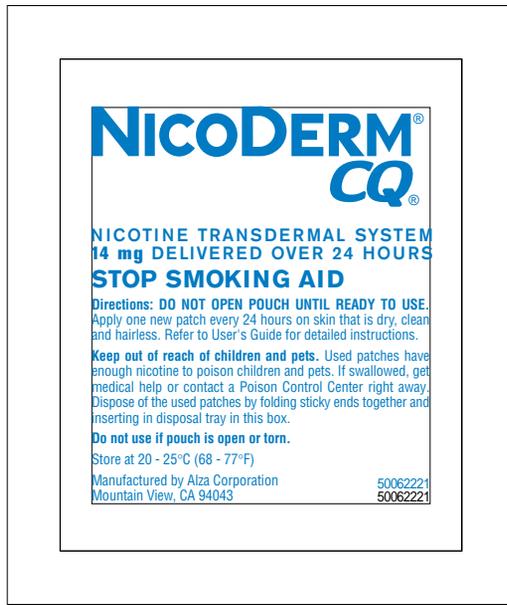
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NicoDerm Opaque Step 2, 14 Count Back and Bottom Flaps



NicoDerm Opaque Step 2, 14 Count End Flaps



NicoDerm Opaque Step 2, Front and Back Pouch



NicoDerm Opaque Step 3, 14 Count Front and Top Flaps

<p>Drug Facts</p> <p>Active ingredient (in each patch) Purpose Nicotine, 7 mg delivered over 24 hours..... Stop smoking aid</p> <p>Use reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking</p> <p>Warnings If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.</p> <p>Do not use</p> <ul style="list-style-type: none"> if you continue to smoke, chew tobacco, use snuff, or use a nicotine gum or other nicotine containing products <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate. high blood pressure not controlled with medication. Nicotine can increase your blood pressure. an allergy to adhesive tape or have skin problems because you are more likely to get rashes <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> using a non-nicotine stop smoking drug taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted. <p>When using this product</p> <ul style="list-style-type: none"> do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your blood stream for several hours after you take off the patch. if you have vivid dreams or other sleep disturbances remove this patch at bedtime <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> skin redness caused by the patch does not go away after four days, or if your skin swells, or you get a rash irregular heartbeat or palpitations occur you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, weakness and rapid heartbeat <p>Keep out of reach of children and pets. Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Dispose of the used patches by folding sticky ends together and inserting in disposal tray in this box.</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> if you are under 18 years of age, ask a doctor before use before using this product, read the enclosed user's guide for complete directions and other information stop smoking completely when you begin using the patch if you smoke more than 10 cigarettes per day, use according to the following 10 week schedule: <table border="1"> <thead> <tr> <th>STEP 1</th> <th>STEP 2</th> <th>STEP 3</th> </tr> </thead> <tbody> <tr> <td>Use one 21 mg patch/day</td> <td>Use one 14 mg patch/day</td> <td>Use one 7 mg patch/day</td> </tr> <tr> <td>Weeks 1-6</td> <td>Weeks 7-8</td> <td>Weeks 9-10</td> </tr> </tbody> </table> <ul style="list-style-type: none"> if you smoke 10 or less cigarettes per day, do not use STEP 1 (21 mg). Start with STEP 2 (14 mg) for 6 weeks, then STEP 3 (7 mg) for 2 weeks and then stop. steps 2 and 3 allow you to gradually reduce your level of nicotine. Completing the full program will increase your chances of quitting successfully. apply one new patch every 24 hours on skin that is dry, clean and hairless remove backing from patch and immediately press onto skin. Hold for 10 seconds. wash hands after applying or removing patch. Throw away the patch in the enclosed disposal tray. See enclosed user's guide for safety and handling. you may wear the patch for 16 or 24 hours if you crave cigarettes when you wake up, wear the patch for 24 hours if you have vivid dreams or other sleep disturbances, you may remove the patch at bedtime and apply a new one in the morning the used patch should be removed and a new one applied to a different skin site at the same time each day do not wear more than one patch at a time do not cut patch in half or into smaller pieces do not leave patch on for more than 24 hours because it may irritate your skin and loses strength after 24 hours stop using the patch at the end of 10 weeks. If you started with STEP 2, stop using the patch at the end of 8 weeks. If you still feel the need to use the patch talk to your doctor. <p>Other information store at 20-25°C(68-77°F)</p> <p>Inactive ingredients ethylene vinyl acetate-copolymer, polyisobutylene and high density polyethylene between pigmented and clear polyester backings</p> <p>Questions or comments? call 1-800-834-5895 weekdays (10:00 a.m. - 4:30 p.m. EST)</p>	STEP 1	STEP 2	STEP 3	Use one 21 mg patch/day	Use one 14 mg patch/day	Use one 7 mg patch/day	Weeks 1-6	Weeks 7-8	Weeks 9-10
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NO PRINT AREA

STOP SMOKING AID



READ THE LABEL

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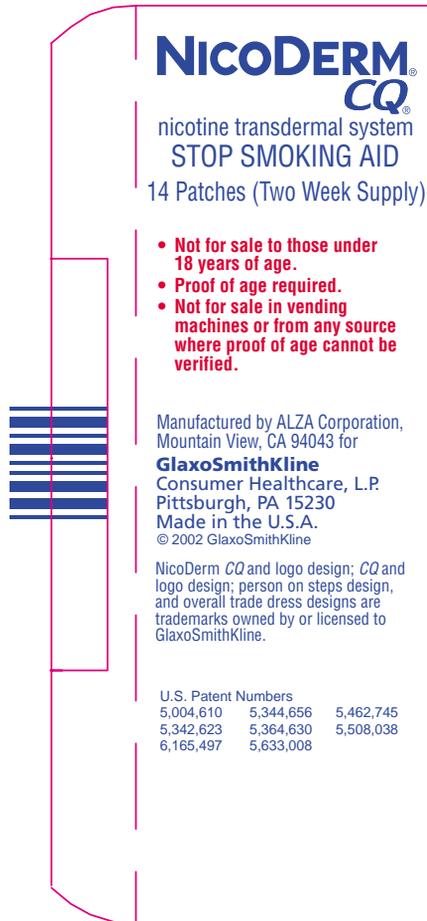


nicotine transdermal system

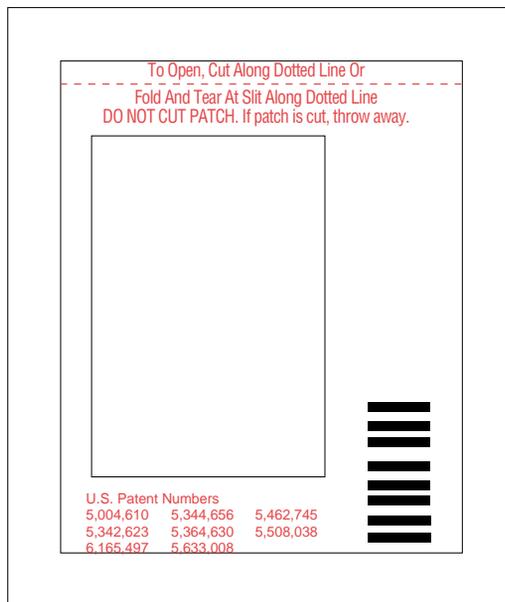
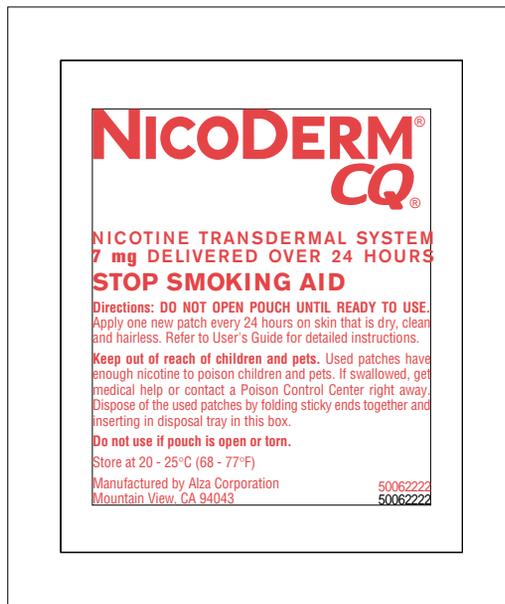
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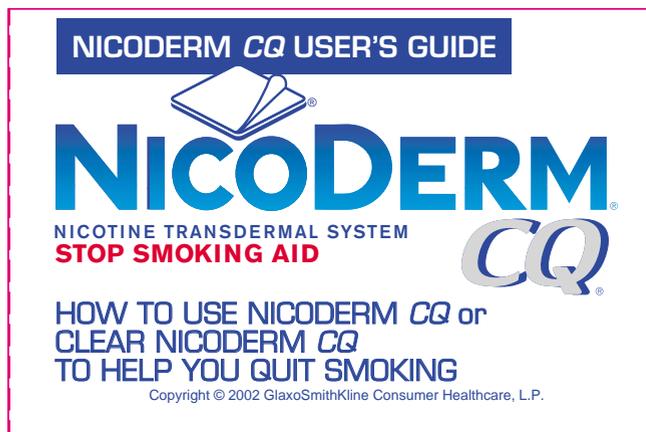
NicoDerm Opaque Step 3, 14 Count Back and Bottom Flaps



NicoDerm Opaque Step 3, 14 Count End Flaps



NicoDerm Opaque Step 3, Front and Back Pouch



NicoDerm CQ User's Guide

PLACE THESE STICKERS ON YOUR CALENDAR:

AT THE BEGINNING OF WEEK #1 (QUIT DATE)

STEP 1
A new 21 mg patch every day



AT THE BEGINNING OF WEEK #7

STEP 2
A new 14 mg patch every day



STEP 3
A new 7 mg patch every day



EX-SMOKER



AT THE BEGINNING OF WEEK #9

WHEN YOU HAVE COMPLETED YOUR QUITTING PROGRAM

For people who smoke 10 or less cigarettes per day: Do not use STEP 1 (21 mg). Use STEP 2 (14 mg) at the beginning of week #1 and STEP 3 (7 mg) at the beginning of week #7.

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KEYS TO SUCCESS

- 1) You must really want to quit smoking for **NicoDerm® CQ®** to help you.
- 2) Complete the full treatment program, applying a new patch every day.
- 3) **NicoDerm CQ** works best when used together with a support program. See page 3 for details.
- 4) If you have trouble using **NicoDerm CQ**, ask your doctor or pharmacist or call GlaxoSmithKline at 1-800-834-5895 weekdays (10:00 a.m. - 4:30 p.m. EST).

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SO, YOU'VE DECIDED TO QUIT.

Congratulations. Your decision to stop smoking is one of the most important things you can do to improve your health. Quitting smoking is a two-part process that involves:

- 1) overcoming your physical need for nicotine, and
- 2) breaking your smoking habit.

NicoDerm CQ helps smokers quit by reducing nicotine withdrawal symptoms. Many NicoDerm CQ users will be able to stop smoking for a few days but often will start smoking again. Most smokers have to try to quit several times before they completely stop.

Your own chances of quitting smoking depend on how strongly you are addicted to nicotine, how much you want to quit, and how closely you follow a quitting plan

like the one that comes with NicoDerm CQ.

QUITTING SMOKING IS HARD!

If you find you cannot stop or if you start smoking again after using NicoDerm CQ, please talk to a health care professional who can help you find a program that may work better for you. Breaking this addiction doesn't happen overnight.

Because NicoDerm CQ provides some nicotine, the NicoDerm CQ patch will help you stop smoking by reducing nicotine withdrawal symptoms such as nicotine craving, nervousness and irritability.

This User's Guide will give you support as you become a non-smoker. It will answer common questions about NicoDerm CQ and give tips to help you stop smoking, and should be referred to often.

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WHERE TO GET HELP.

You are more likely to stop smoking by using NicoDerm CQ with a support program that helps you break your smoking habit. There may be support groups in your area for people trying to quit. Call your local chapter of the American Lung Association, American Cancer Society or American Heart Association for further information. Toll free phone numbers are printed on the wallet card on the back cover of this User's Guide.

If you find you cannot stop smoking or if you start smoking again after using NicoDerm CQ, remember breaking this addiction doesn't happen overnight. You may want to talk to a health care professional who can help you improve

your chances of quitting the next time you try NicoDerm CQ or another method.

LET'S GET ORGANIZED.

Your reason for quitting may be a combination of concerns about health, the effect of smoking on your appearance, and pressure from your family and friends to stop smoking. Or maybe you're concerned about the dangerous effect of second-hand smoke on the people you care about.

All of these are good reasons. You probably have others. Decide your most important reasons, and write them down on the wallet card inside the back cover of this User's Guide. Carry this card with you. In difficult moments, when you want to smoke, the card will remind you why you are quitting.

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WHAT YOU'RE UP AGAINST.

Smoking is addictive in two ways. Your need for nicotine has become both physical and mental. You must overcome both addictions to stop smoking. So while NicoDerm CQ will lessen your body's craving for nicotine, you've got to want to quit smoking to overcome the mental dependence on cigarettes. Once you've decided that you're going to quit, it's time to get started. But first, there are some important warnings you should consider.

SOME IMPORTANT WARNINGS.

This product is only for those who want to stop smoking.

If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop

smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

Do not use

- if you continue to smoke, chew tobacco, use snuff, or use a nicotine gum or other nicotine containing products.

Ask a doctor before use if you have

- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase your blood pressure.
- an allergy to adhesive tape or have skin problems because you are more likely to get rashes.

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Ask a doctor or pharmacist before use if you are

- using a non-nicotine stop smoking drug.
- taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

When using this product

- do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your bloodstream for several hours after you take off the patch.
- if you have vivid dreams or other sleep disturbances remove this patch at bedtime.

Stop use and ask a doctor if

- skin redness caused by the patch does not go away after four days, or if your skin swells, or you get a rash.
- irregular heartbeat or palpitations occur.

- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, weakness and rapid heartbeat.

Keep out of reach of children and pets.

Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or contact a Poison Control Center right away. Dispose of the used patches by folding sticky ends together and inserting in disposal tray in this box.

LET'S GET STARTED.

If you are under 18 years of age, ask a doctor before use.

Becoming a non-smoker starts today. Your first step is to read through this entire User's Guide carefully.

First, check that you bought the right starting dose.

If you smoke more than 10 cigarettes per day, begin with Step 1 (21 mg). As the

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carton indicates, people who smoke 10 or less cigarettes per day should not use Step 1 (21 mg). They should start with Step 2 (14 mg). Throughout this User's Guide we will give specific instructions for people who smoke 10 or less cigarettes per day.

Next, set your personalized quitting schedule.

Take out a calendar that you can use to track your progress. Pick a quit date, and mark this on your calendar using the stickers inside the front cover of this User's Guide, as described below.

Directions: For People who smoke more than 10 cigarettes per day:

STEP 1 (Weeks 1-6). Your quit date (and the day you'll start using NicoDerm CQ patch).



Choose your quit date (it should be soon). This is the day you will quit smoking cigarettes entirely and begin using NicoDerm CQ to reduce your cravings for nicotine. Place the Step 1 sticker on this date. For the first six weeks, you'll use the highest-strength (21 mg) NicoDerm CQ patches. Be sure to follow the directions on page 10.

Completing the full program will increase your chances of quitting successfully. This is done by changing over to the Step 2 (14 mg) patch for 2 weeks followed by a final 2 weeks with the Step 3 (7 mg) patch. The Step 2 and Step 3 treatment period allows you to gradually reduce the amount of nicotine you get, rather than stopping suddenly, and will increase your chances of quitting.

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STEP 2 (Weeks 7-8). The day you'll start reducing your use of NicoDerm CQ patch.

Switching to Step 2 (14 mg) patches after 6 weeks begins to gradually reduce your nicotine usage. Place the Step 2 sticker on this date (the first day of week seven). Use the 14 mg patches for two weeks.

STEP 3 (Weeks 9-10). The day you'll further start reducing your use of NicoDerm CQ patch.

After eight weeks, nicotine intake is further reduced by moving down to Step 3 (7 mg) patches. Place the Step 3 sticker on this date (the first day of week nine). Use the 7 mg patches for two weeks.

THE NICODERM CQ PROGRAM

STEP 1	STEP 2	STEP 3
Use one 21 mg patch/day	Use one 14 mg patch/day	Use one 7 mg patch/day
Weeks 1-6	Weeks 7-8	Weeks 9-10

STOP USING NICODERM CQ AT THE END OF WEEK 10

If you still feel the need to use NicoDerm CQ after Week 10, talk with your doctor or health professional.

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Directions: For People who smoke 10 or less cigarettes per day. Do not use STEP 1 (21 mg). Begin with STEP 2 – Initial Treatment Period (Weeks 1-6): 14 mg patches. Choose your quit date (it should be soon). This is the day you will quit smoking cigarettes entirely and begin using NicoDerm CQ to reduce your cravings for nicotine. Place the Step 2 sticker on this date. For the first six weeks, you'll use the Step 2 (14 mg) NicoDerm CQ patches. Be sure to follow the directions on page 10. **Continue with STEP 3 – Step Down Treatment Period (Weeks 7-8): 7 mg patches.** Completing the full program will increase your chances of quitting successfully. This is done by changing over to the Step 3 (7 mg) patches for 2 weeks. The two week step down treatment period allows you to

gradually reduce the amount of nicotine you get, rather than stopping suddenly, and will increase your chances of quitting. Place the Step 3 sticker on the first day of week seven. Use the 7 mg patches for two weeks.

People who smoke 10 or less cigarettes per day should not use NicoDerm CQ for longer than 8 weeks. If you still feel the need to use NicoDerm CQ after 8 weeks, talk with your doctor.

PLAN AHEAD.

Because smoking is an addiction, it is not easy to stop. After you've given up nicotine, you may still have a strong urge to smoke. Plan ahead NOW for these times, so you're not tempted to start smoking again in a moment of weakness. The following tips may help:

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- Keep the phone numbers of supportive friends and family members handy.
- Keep a record of your quitting process. In the event that you slip, immediately stop smoking and resume your quit attempt by using the NicoDerm CQ patch. If you smoke at all, write down what you think caused the slip.
- Put together an Emergency Kit that includes items that will help take your mind off occasional urges to smoke. You might include cinnamon gum or lemon drops to suck on, a relaxing cassette tape, and something for your hands to play with, like a smooth rock, rubber band, or small metal balls.
- Set aside some small rewards, like a new magazine or a gift certificate from your favorite store, which you'll "give" yourself after passing difficult hurdles.
- Think now about the times when you most often want a cigarette, and then plan what else you might do instead of smoking. For instance, you might plan to take your coffee break in a new location, or take a walk right after dinner, so you won't be tempted to smoke.

HOW NICODERM CQ WORKS.

NicoDerm CQ patches provide nicotine to your system. They work as a temporary aid to help you quit smoking by reducing nicotine withdrawal symptoms, including nicotine craving. NicoDerm CQ provides a lower level of nicotine to your blood than cigarettes, and allows you to gradually do away with your body's need for nicotine.



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Because NicoDerm CQ does not contain the tar or carbon monoxide of cigarette smoke, it does not have the same health dangers as tobacco. However, it still delivers nicotine, the addictive part of cigarette smoke. Nicotine can cause side effects such as headache, nausea, upset stomach, and dizziness.

HOW TO USE NICODERM CQ PATCHES.

Read all the following instructions, and the instructions on the outer carton, before using NicoDerm CQ. Refer to them often to make sure you're using NicoDerm CQ correctly. Please refer to the compact disc for additional help.

- 1) Stop smoking completely before you start using NicoDerm CQ.
- 2) To reduce nicotine craving and other

withdrawal symptoms, use NicoDerm CQ according to the directions on pages 6-8.

- 3) Insert used NicoDerm CQ patches in the child resistant disposal tray provided in the box — safely away from children and pets.

When to apply and remove NicoDerm CQ patches.

Each day apply a new patch to a different place on skin that is dry, clean and hairless. **You can wear a NicoDerm CQ patch for either 16 or 24 hours.** If you crave cigarettes when you wake up, wear the patch for 24 hours. If you begin to have vivid dreams or other disruptions of your sleep while wearing the patch 24 hours, try taking the patch off at bedtime (after about 16 hours) and putting on a new one when you get up the next day.

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What is **COMMITTED** *Quitters*[®]

- A **FREE**, custom-tailored plan to help you break the psychological addiction to smoking.
- Throughout your quit attempt, you will receive personalized advice on how to cope with situations that make you want to smoke.



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Personalized Stop Smoking Plan

**To Enroll Call Now
1-800-770-0708**



or enroll online at
www.committedquitters.com

and ask for your **FREE**
**Personalized Stop
Smoking Plan**

- Provide your **PERSONAL CODE**, printed on the back of this card.
- You will be personally interviewed by a plan specialist to understand your specific needs and to design a Stop Smoking Plan just for you.

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PERSONAL CODE



Personalized Stop Smoking Plan brought to you by



and
GlaxoSmithKline Consumer Healthcare, L.P.

NicoDerm, CQ, Nicorette, Committed Quitters and associated logo designs,
person on steps designs, and overall trade dress designs are trademarks
owned by or licensed to GlaxoSmithKline.

Call Between 7 am and 12 midnight EST or enroll online
24 hours a day

(ONE PLAN PER CUSTOMER) © 2002 GlaxoSmithKline
Read and follow label directions

Do not smoke even when you are not wearing the patch.

Remove the used patch and put on a new patch at the same time every day. Applying the patch at about the same time each day (first thing in the morning, for instance) will help you remember when to put on a new patch. Do not leave the same NicoDerm CQ patch on for more than 24 hours because it may irritate your skin and because it loses strength after 24 hours. Do not use NicoDerm CQ continuously for more than 10 weeks (8 weeks for people who smoke 10 or less cigarettes per day).

How to apply a NicoDerm CQ patch.

1. Do not remove the NicoDerm CQ patch from its sealed protective pouch until you are ready to use it. NicoDerm CQ patches will lose nicotine to the air if you store them out of the pouch.

2. Choose a non-hairy, clean, dry area of skin. Do not put a NicoDerm CQ patch on skin that is burned, broken out, cut, or irritated in any way. Make sure your skin is free of lotion and soap before applying a patch.



3. A clear, protective liner covers the sticky back side of the NicoDerm CQ patch — the side that will be put on your skin. The liner has a slit down the middle to help you remove it from the patch. With the sticky back side facing you, pull half the liner away from the NicoDerm CQ patch starting at the middle slit, as shown in the illustration above. Hold the NicoDerm CQ patch at one of the outside edges (touch the sticky side as little as possible), and pull off the other half of the protective liner.

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Place this liner in the slot in the disposal tray provided in the NicoDerm CQ package where it will be out of reach of children and pets.

4. Immediately apply the sticky side of the NicoDerm CQ patch to your skin. **Press the patch firmly on your skin with the heel of your hand for at least 10 seconds.** Make sure it sticks well to your skin, especially around the edges.



5. Wash your hands when you have finished applying the NicoDerm CQ patch. Nicotine on your hands could get into your eyes and nose, and cause stinging, redness, or more serious problems.



6. After 24 or 16 hours, remove the patch you have been wearing. Fold the used NicoDerm CQ patch in half with the sticky side together. Carefully dispose of the used patch in the slot of the disposal tray provided in the NicoDerm CQ package where it will be out of the reach of children and pets. Even used patches have enough nicotine to poison children and pets. Wash your hands.
7. Choose a different place on your skin to apply the next NicoDerm CQ patch and repeat Steps 1 to 6. Do not apply a new patch to a previously used skin site for at least one week.



If your NicoDerm CQ patch gets wet during wearing.

Water will not harm the NicoDerm CQ

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patch you are wearing if applied properly. You can bathe, swim, or shower for short periods while you are wearing the NicoDerm CQ patch.

If your NicoDerm CQ patch comes off while wearing.

NicoDerm CQ patches generally stick well to most people's skin. However, a patch may occasionally come off. If your NicoDerm CQ patch falls off during the day, put on a new patch, making sure you select a non-hairy, non-irritated area of skin that is clean and dry.

If the soap you use has lanolin or moisturizers, the patch may not stick well. Using a different soap may help. Body creams, lotions and sunscreens can also cause problems with keeping your patch on. Do not apply creams or

lotions to the place on your skin where you will put the patch.

If you have followed the directions and the patch still does not stick to you, try using medical adhesive tape over the patch.

Disposing of NicoDerm CQ patches.

Fold the used patch in half with the sticky side together. Carefully dispose of the patch in the disposal slot of the tray provided in the NicoDerm CQ package where it will be out of the reach of children and pets. Small amounts of nicotine, even from a used patch, can poison children and pets. **Keep all nicotine patches away from children and pets.** Wash your hands after disposing of the patch.



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If your skin reacts to the NicoDerm CQ patch.

When you first put on a NicoDerm CQ patch, mild itching, burning, or tingling is normal and should go away within an hour. After you remove a NicoDerm CQ patch, the skin under the patch might be somewhat red. Your skin should not stay red for more than a day after removing the patch. **Stop use and ask a doctor if skin redness caused by the patch does not go away after four days, or if your skin swells, or you get a rash. Do not put on a new patch.**

Storage Instructions.

Keep each NicoDerm CQ patch in its protective pouch, unopened, until you are ready to use it, because the patch will lose nicotine to the air if it's outside the pouch.



Store NicoDerm CQ patches at 20-25°C (68-77°F) because they are sensitive to heat. Remember, the inside of your car can reach temperatures much higher than this. A slight yellowing of the sticky side of the patch is normal.

Do not use NicoDerm CQ patches stored in pouches that are open or torn.

TIPS TO MAKE QUITTING EASIER.

Within the first few weeks of giving up smoking, you may be tempted to smoke for pleasure, particularly after completing a difficult task, or at a party or bar. Here are some tips to help get you through the important first stages of becoming a non-smoker:

On Your Quit Date:

- Ask your family, friends and co-workers to support you in your efforts to stop smoking.

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- Throw away all your cigarettes, matches, lighters, ashtrays, etc.
 - Keep busy on your quit day. Exercise. Go to a movie. Take a walk. Get together with friends.
 - Figure out how much money you'll save by not smoking. Most ex-smokers can save more than \$1,000 a year on the price of cigarettes alone.
 - Write down what you will do with the money you save.
 - Know your high risk situations and plan ahead how you will deal with them.
 - Visit your dentist and have your teeth cleaned to get rid of the tobacco stains.
- Right after Quitting:**
- During the first few days after you've stopped smoking, spend as much time as possible at places where smoking is not allowed.
 - Drink large quantities of water and fruit juices.
 - Try to avoid alcohol, coffee and other beverages you associate with smoking.
 - Remember that temporary urges to smoke will pass, even if you don't smoke a cigarette.
 - Keep your hands busy with something like a pencil or a paper clip.
 - Find other activities that help you relax without cigarettes. Swim, jog, take a walk, play basketball.
 - Don't worry too much about gaining weight. Watch what you eat, take time for daily exercise, and change your eating habits if you need to.

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- Laughter helps. Watch or read something funny.

WHAT TO EXPECT.

The First Few Days.

Your body is now coming back into balance. During the first few days after you stop smoking, you might feel edgy and nervous and have trouble concentrating. You might get headaches, feel dizzy and a little out of sorts, feel sweaty or have stomach upsets. You might even have trouble sleeping at first. These are typical nicotine withdrawal symptoms that will go away with time. Your smoker's cough will get worse before it gets better. But don't worry, that's a good sign. Coughing helps clear the tar deposits out of your lungs.

After A Week Or Two.

By now you should be feeling more confident that you can handle those smoking urges. Many of your nicotine withdrawal symptoms have left by now, and you should be noticing some positive signs: less coughing, better breathing and an improved sense of taste and smell, to name a few.

After A Month.

You probably have the urge to smoke much less often now. But urges may still occur, and when they do, they are likely to be powerful ones that come out of nowhere. Don't let them catch you off guard. Plan ahead for these difficult times. Concentrate on the ways non-smokers are more attractive than smokers. Their skin is less likely to wrinkle. Their teeth are whiter, cleaner. Their breath is fresher.

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Their hair and clothes smell better. That cough that seems to make even a laugh sound more like a rattle is a thing of the past. Their children and others around them are healthier, too.

What To Do About Relapse.

What should you do if you slip and start smoking again? The answer is simple. A lapse of one or two or even a few cigarettes should not spoil your efforts! Throw away your cigarettes, forgive yourself and continue with the program. Listen to the Compact Disc again and re-read the User's Guide to ensure that you're using NicoDerm CQ correctly and following the other important tips for dealing with the mental and social dependence on nicotine. Your doctor, pharmacist or other health professional can also provide useful counseling on the

importance of stopping smoking. You should consider them partners in your quit attempt.

What To Do About Relapse After a Successful Quit Attempt.

If you have taken up regular smoking again, don't be discouraged. Research shows that the best thing you can do is try again, since several quitting attempts may be needed before you're successful. And your chances of quitting successfully increase with each quit attempt.

The important thing is to learn from your last attempt.

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- Admit that you've slipped, but don't treat yourself as a failure.
- Try to identify the "trigger" that caused you to slip, and prepare a better plan for dealing with this problem next time.
- Talk positively to yourself – tell yourself that you have learned something from this experience.
- Make sure you used NicoDerm CQ patches correctly.
- Remember that it takes practice to do anything, and quitting smoking is no exception.

WHEN THE STRUGGLE IS OVER.

Once you've stopped smoking, take a second and pat yourself on your back. Now do it again. You deserve it.

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Remember now why you decided to stop smoking in the first place. Look at your list of reasons. Read them again. And smile.

Now think about all the money you are saving and what you'll do with it. All the non-smoking places you can go, and what you might do there. All those years you may have added to your life, and what you'll do with them. Remember that temptation may not be gone forever. However, the hard part is behind you so look forward with a positive attitude, and enjoy your new life as a non-smoker.

QUESTIONS & ANSWERS.

1. How will I feel when I stop smoking and start using NicoDerm CQ?

You'll need to prepare yourself for some nicotine withdrawal symptoms. These begin almost immediately after you stop

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smoking, and are usually at their worst during the first three or four days. Understand that any of the following is possible:

- craving for nicotine
- anxiety, irritability, restlessness, mood changes, nervousness
- disruptions of your sleep
- drowsiness
- trouble concentrating
- increased appetite and weight gain
- headaches, muscular pain, constipation, fatigue.

NicoDerm CQ reduces nicotine withdrawal symptoms such as irritability and nervousness, as well as the craving for nicotine you used to satisfy by having a cigarette.

2. Is NicoDerm CQ just substituting one form of nicotine for another?

NicoDerm CQ does contain nicotine. The purpose of NicoDerm CQ is to provide you with enough nicotine to reduce the physical withdrawal symptoms so you can deal with the mental aspects of quitting.

3. Can I be hurt by using NicoDerm CQ?

For most adults, the amount of nicotine delivered from the patch is less than from smoking. If you believe you may be sensitive to even this amount of nicotine, you should not use this product without advice from your doctor. There are also some important warnings in this User's Guide (See page 4).

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4. Will I gain weight?

Many people do tend to gain a few pounds the first 8-10 weeks after they stop smoking. This is a very small price to pay for the enormous gains that you will make in your overall health and attractiveness. If you continue to gain weight after the first two months, try to analyze what you're doing differently. Reduce your fat intake, choose healthy snacks, and increase your physical activity to burn off the extra calories. Drink lots of water. This is good for your body and skin, and also helps to reduce the amount you eat.

5. Is NicoDerm CQ more expensive than smoking?

The total cost of the NicoDerm CQ program is similar to what a person who smokes one and a half packs of cigarettes

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a day would spend on cigarettes for the same period of time. Also, use of NicoDerm CQ is only a short-term cost, while the cost of smoking is a long-term cost, including the health problems smoking causes.

6. What if I slip up?

Discard your cigarettes, forgive yourself and then get back on track. Don't consider yourself a failure or punish yourself. In fact, people who have already tried to quit are more likely to be successful the next time.

GOOD LUCK!

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• Not for sale to those under 18 years of age.

- Proof of age required.
- Not for sale in vending machines or from any source where proof of age cannot be verified.

WALLET CARD

My most important reasons to quit smoking are:

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WALLET CARD

WHERE TO CALL FOR HELP:

American Lung Association 800-586-4872	American Cancer Society 800-227-2345	American Heart Association 800-242-8721
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For People who smoke more than 10 cigarettes per day:

STEP 1	STEP 2	STEP 3
Use one 21 mg patch/day	Use one 14 mg patch/day	Use one 7 mg patch/day
Weeks 1-6	Weeks 7-8	Weeks 9-10

People who smoke 10 or less cigarettes per day: Do not use STEP 1 (21 mg). Use STEP 2 (14 mg) for six weeks and STEP 3 (7 mg) for two weeks and then stop.

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NicoDerm CQ Audio (CD) Transcript

**NicoDerm CQ Audio (CD version)
Side A, Section 1**

SFX: Sound of various voices from happy crowd.

ANNCR: Congratulations on your decision to become a non-smoker. This is one of the most important decisions you'll ever make. And one of the best.

(**VOICES:** Yeah! Right! Way to go!)

The NicoDerm CQ patch User's Guide, carton labeling, and this audio CD are designed to help make it as easy as possible to break the habit. But keep in mind that this program won't work unless you're really committed to becoming a non-smoker. It's not easy to stop smoking, but you've taken the most difficult step by making the decision to quit. Now, maybe you tried before and failed. If so, don't be discouraged. Remember, lots of people make a couple of tries before they succeed.

(**VOICE:** Yeah -- you can do it!)

You have to remember that NicoDerm CQ helps with the physical part of your addiction to cigarettes, but it can't deal with the mental part. And that's harder than the physical part for many people. Pure and simple, it takes willpower. But don't panic -- we'll be supporting you there, too. We've got some suggestions that will really help. One reason your willpower may not be up to the job is that you'll still have a strong physical craving for nicotine. With NicoDerm CQ that shouldn't be a major problem. But there are a lot of things that tend to make you reach for a smoke. Plain old force of habit, for one.

Fortunately, there are some pretty effective techniques for dealing with the mental addiction, and for boosting your willpower. We'll talk more about them later on.

(**ANNCR:** speaks man-to-man to listener.)

Let me start by giving you some serious and important information. NicoDerm CQ is a carefully designed, easy-to-use patch containing nicotine, which it releases into your body through your skin at a controlled rate. Even though it seems to be a simple product, it's serious medicine, and like any medicine, you should use it only as directed. We'll get to the directions later, but you should also know that there are some people who shouldn't use NicoDerm CQ or any product containing nicotine without checking with their health professional.

Anyone with heart disease, recent heart attack or irregular heartbeat should ask their doctor before using NicoDerm CQ. Nicotine can increase your heart rate. If you have high blood pressure not controlled with medication you should also ask your doctor before using NicoDerm CQ, since nicotine can increase your blood pressure. If you take prescription medicine for depression or asthma talk to your doctor before use because your prescription dose may need to be adjusted. And if you are allergic to adhesive tape or have skin problems, you should also ask your doctor if you should use NicoDerm CQ.

If pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

Be sure to read the User's Guide that comes in this kit for other important information about using NicoDerm CQ.

(**VOICE:** "Tell 'em the good news.")

ANNCR: Okay. Even though NicoDerm CQ contains nicotine, it doesn't contain any of the thousands of other harmful chemicals that are in cigarette smoke. And it's designed to get you off nicotine for good. That's a good deal, right?

(**VOICES:** "It worked for me." "Yeah!" "Go for it!")

ANNCR: Now let's get back to the celebration. The person listening to this CD is on the way to taking control of his or her life and kicking the cigarette habit for good. So let's hear it for 'em!

(**SFX:** Wild cheering. Fade...)

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NicoDerm CQ audio (CD version)
Side A, Section 2

Support group. Adults. Group leader is authoritative but pleasant man. Among students are Older Woman (OW), Young Woman (YW) Young Man (YM), and cynical Older Man with gruff voice (OM).

(SFX: Murmurs, conversation. Leader raps on desk for attention.)

LEADER: All right; quiet now. This support group is all about how to use NicoDerm CQ to help you quit smoking.

OM: So who needs a support group? It's a patch. You stick it on your skin. We might as well have to take a class on how to breathe.

LEADER: How to Breathe is Mr. Yamato's group, down the hall. You'll be in that one later. But this comes first because NicoDerm CQ isn't as simple as a plastic bandage. You have to use it the right way or it won't work the way it's designed to.

OM: Hey, this is kid's stuff.

LEADER: It certainly isn't. NicoDerm CQ is only for adults who want to quit smoking. That's someone at least 18 years old. Younger people should talk to a doctor first.

Okay, let's begin. First, has everybody read the NicoDerm CQ User's Guide?

OW: I read it. It didn't take long and it made the whole quitting process a lot clearer to me.

LEADER: There's nothing mysterious or complicated about it. But there's a right way to do it, and the only way you can expect to get the results you want is to use NicoDerm CQ the way it's designed to be used.

Now, who remembers the very first instruction?

OW: Buy NicoDerm CQ patches?

LEADER: Actually, there's an even earlier step. Before using NicoDerm CQ you have to stop smoking -- and I mean completely. That's important! And you mustn't chew tobacco or use snuff, nicotine gum, or other nicotine containing products either.

You start using NicoDerm CQ on the day you stop smoking, and you never smoke and use NicoDerm CQ together. That could give you an overdose of nicotine, which is pretty powerful stuff. The results could make you sick.

YW: I know. Sometimes if I smoke two or three cigarettes in a row, like if I'm nervous, I get dizzy.

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LEADER: Sure. Now, you know that you have to stop smoking completely before you start using NicoDerm CQ. The next question is: when are you going to stop? Has everybody picked a Quit Date?

OM: Yeah, I have. I have to attend a seminar on Monday, in a nonsmoking building. I figure if NicoDerm CQ can get me through the first day, it'll be easier from then on.

LEADER: Not a bad idea. Just be careful. When you walk out of that building, there's going to be a terrific desire to have a smoke, so you have to be prepared for that. The NicoDerm CQ User's Guide includes a list of tips for handling those temptations, which we'll talk about in a little while. Anybody else?

OW: I'm going to quit as soon as possible. After I take today's classes I'm going to stop smoking. I already marked tomorrow on my calendar.

LEADER: That's it. Pick a date and stick with it. How about you, miss?

YW: My cousin is visiting this weekend. I figure I'll be so busy showing her around, I won't have time to think about wanting to smoke! And if I am tempted to slip, she could talk me out of it.

LEADER: Actually, the idea of having support when you need it is a good one. A friend or family member, maybe even a co-worker, can provide moral support. Or, you can join a group of people who are trying to quit, just like you. Several national organizations offer support groups like this one - there's a list of their toll-free phone numbers on the back cover of the NicoDerm CQ User's Guide. They can help you find a support group in your area.

LEADER: Now, we have to learn how to use NicoDerm CQ.

OM: What's the big deal about that?

LEADER: It's not a big deal, but it's important. As I said before, you have to do it right. The first thing you have to know is that there are three different NicoDerm CQ patches.

OW: I know -- it was in the book. I smoke about 20 cigarettes a day so I bought a Step 1 pack. For the first 6 weeks, you use the 21 milligram patches. The carton says that completing the full program will increase your chances of quitting successfully. You do this by changing over to the Step 2 (14 milligram) patches for two weeks, followed by a final two weeks with the Step 3 (7 milligram) patches. The four week step down treatment period allows you to gradually reduce the amount of nicotine you get, rather than stopping suddenly, and will increase your chances of quitting.

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LEADER: Right -- you gradually reduce your nicotine intake, so your body gets used to a lower level of nicotine.

OM: How do I tell the difference between the patches?

LEADER: The packages are clearly marked. Now, did you get the schedule? For the first six weeks you apply the Step 1 patch -- that's the 21 milligram one with the pouch printed in green -- every day at about the same time. Most people put on a new one every morning.

Completing a full program will increase your chances of quitting successfully. This is done by changing over to the Step 2 patch -- the 14 milligram size with the pouch printed in blue -- for two weeks - that's every day during weeks 7 & 8.

Nicotine intake is further reduced by moving down to the Step 3 patch for the final two weeks -- that's every day during weeks 9 & 10. That's the 7 milligram one with the pouch printed in red. Then you stop using NicoDerm CQ completely.

YM: That sounds easy enough. Six weeks with Step 1, two weeks with Step 2 and two weeks with Step 3. But what about people, like me, who smoke 10 or less cigarettes per day?

LEADER: People who smoke 10 or less cigarettes per day like you should not use the Step 1 (21 milligram) patch. You should start with the Step 2 patch - that's the 14 milligram one with the pouch printed in blue - for the first six weeks. Then you reduce your nicotine intake further by using the Step 3 patch - the 7 milligram size with the pouch printed in red -- for two weeks - that's weeks 7 and 8. Then you stop completely.

YM: Great. Six weeks with Step 2 and two weeks with Step 3, if you smoke 10 cigarettes or less a day. Sounds easy.

OM: How long do we wear the patches? The carton said something about 24 hours or 16 hours?

LEADER: That's up to you. If you crave cigarettes when you wake up, you should wear the patch for 24 hours. If you begin to have vivid dreams or other disruptions of your sleep while wearing the patch for 24 hours, try taking the patch off at bedtime (after about 16 hours) and putting on a new one when you get up the next day. Otherwise, simply take the old patch off the next morning and put on a new one in a different place. But remember, if you use the patch for 16 hours, do not smoke even when you are not wearing the patch.

YW: OK, but why put a new patch on in a different place?

LEADER: Because like any kind of patch, NicoDerm CQ may redden your skin a little. That's normal, but it's best to avoid using the same spot for a week or so. Now, this is something else that's very important: Stop use and ask a doctor if skin redness

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caused by the patch does not go away after four days, or if your skin swells, or you get a rash.

OW: Any places you shouldn't put it?

LEADER: Well, you probably wouldn't want to put it on your face or other sensitive skin. Aside from that it doesn't much matter -- arm, leg, chest, back -- whatever is most comfortable for you. Of course, you should avoid areas with a lot of hair. When it's time to remove the patch, you'll be glad you did!

YW: Do these things stick pretty tight?

LEADER: Yes, if you apply them to clean, dry skin that doesn't have any lotion or cream on it. Those things could keep it from sticking properly. I have a patch here; let's take a look at how to apply it. Do I have a volunteer?
(*Momentary silence..*)

YM: Well, I guess you can stick it on me.

LEADER: No, you're going to do it yourself. The rest of you can watch. Now, first peel the protective lining off the patch. And by the way, don't remove the protective liner until you're ready to apply the patch. See, the lining is split down the middle to make it easier.

YM: Okay ... that's one side ... and the other side. There!

LEADER: The side that has the adhesive on it goes against your skin. Now, where are you going to put it?

YM: Let's see. I don't necessarily want it showing, so I guess I'll roll up my sleeve and stick it on the inside of my arm up here.

LEADER: Okay, that's a good spot. Not much hair there. Now press it on firmly with the heel of your hand, and hold it for about ten seconds.

YM: How come?

LEADER: Pressure is what activates the adhesive - you need to hold the pressure for a while to make sure it stays put. Check the edges to see that they stick.

YM: It's on there pretty good. That's it, huh?

LEADER: Not quite. You have to throw away the protective lining in a safe place -- where children or pets can't get at it - because it has nicotine on it.

YM: Should I put the protective liner through the slot in the disposal tray that comes with NicoDerm CQ?

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LEADER: Yes, you should. In that way you'll dispose of the liner safely away from children and pets. The disposal tray is child resistant.

Now, it's important to wash your hands because they have a bit of nicotine on them, and you don't want to get it into your eyes or mouth.

Of course, this is a dummy patch without any nicotine in it. You mustn't apply a real NicoDerm CQ patch until your Quit Date.

YM: Can I take this off now?

LEADER: Sure. Just peel it back parallel to your skin, the way you'd remove a plastic bandage.

YM: Right. Hey, that's not too bad. It sticks, but it's not too hard to get off. I thought it was going to pull a lot more.

LEADER: Don't forget - if that were a real patch it would still have nicotine in it, so you'd have to dispose of it safely. Fold the patch in half so that the sides stick together. Put the patch through the slot in the disposal tray provided in each NicoDerm CQ box, just like the protective liner. Then wash your hands.

YM: Won't it come off if I go swimming?

LEADER: It shouldn't. You can shower, bathe or even swim for short periods without affecting it. Incidentally, a little itching or tingling is normal for the first hour or so after you apply a patch. That's ok, and it goes away after a while.

One more thing. Store NicoDerm CQ patches properly. Don't keep your patches in a hot place like the glove compartment of your car. They can lose strength if you do. You should store the patches at 20 to 25 degrees Centigrade, that's 68 to 77 degrees Fahrenheit.

OM: There's more to this stuff than meets the eye. I guess it was worth being here after all.

LEADER: I'm glad you feel that way. Everything we've gone over here is explained very clearly in your User's Guide, so everyone be sure to read it all the way through.

Now, let's review the schedule. What patch do you start with and how long do you use it?

YW: I know. If you smoke more than 10 cigarettes per day, you use the Step 1 patch for six weeks.

LEADER: Good, that is STEP 1, the first step. How about after that?

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OW: You begin to gradually reduce the amount of nicotine you get by starting the step down treatment period. This is done by changing to the Step 2 patch for the next two weeks, followed by a final two weeks with the Step 3 patch. Completing the full program will increase your chances of quitting successfully.

LEADER: And after that?

(Momentary silence.)

OW: Why, nothing. You stop.

LEADER: Exactly. Don't use NicoDerm CQ for more than ten weeks. That should be long enough for you to kick the cigarette habit.

OM: But what if I get the urge after that?

LEADER: You should actually be over the physical part of your nicotine addiction by that time. It's the mental addiction that might be the hardest part to fight. If you still feel the need for NicoDerm CQ, talk with your doctor.

YM: What about people who smoke 10 or less cigarettes per day?

LEADER: People who smoke 10 cigarettes or less a day -- should not use the Step 1 (21 milligram) patch. They should start with the Step 2 patch -- that's the 14 milligram one with the pouch printed in blue -- for the first six weeks. Completing a full program will increase your chances of quitting successfully. This is done by stepping down to the Step 3 patch -- the 7 milligram ones with the pouch printed in red -- for two weeks. That's every day during weeks 7 & 8. People who smoke 10 or less cigarettes per day should not use NicoDerm CQ for more than 8 weeks.

Now before you all head down to your next group, don't forget to pick your Quit Date, and mark your calendar. Paste the stickers on your calendars when you plan to switch to the lower dose patches. And good luck to you all!

(People get up and begin shuffling out of the room.)

OM (to OW): Stickers? What stickers?

OW: There's a set of stickers in the User's Guide you can use to mark your calendar with.

(END OF SIDE A)

NicoDerm CQ Audio (CD version)
Side B

(Music. Peaceful and soothing. Perhaps "space music" with vaguely oriental harmonies.)

Mr. Yamato's classroom. The students have filed in, and are strangely quiet. (Music down.)

Mr. Yamato has almost no accent, and speaks somewhat precisely in a soft voice that is reassuring and comforting.

YAMATO: Good afternoon. I notice that you are all rather quiet. That is because of the music. It is true that peaceful music brings a quiet and relaxed state of mind. (Music down and out.) One of the things you will see as you go through your program to end your smoking habit is that relaxation is important in relieving the mental stress you may feel.

But before we become too relaxed, I would like each of you to tell me your most important reason for wanting to quit. Let's begin with you, miss.

YW: Oh. Well, I guess I want to quit because I don't want to smell like smoke all the time. I put on this expensive perfume, but I still smell like smoke. I don't now because I haven't had a cigarette for a couple of hours while I'm in school here.

YAMATO: Things will smell even better to you after you have been off cigarettes for a while. Things will smell better and taste better. But that probably isn't your most important reason for quitting, sir.

YM: Oh, no. I want to quit basically because I figure it will be a lot better for my health. Right now, when I work out or play a little basketball I get winded pretty easy.

YAMATO: That's the best reason of all. You have all read the many reports that tie cigarette smoking to some serious diseases and health problems. As soon as you stop smoking, your risk of getting these diseases begins to decrease.

OW: I'm quitting for my health too. But I also have my niece and her two children living with me, and I don't think living in a smoky, house is good for them. So I guess I'm doing it for all of us.

OM: Yeah, well my wife is the one who started bugging me. She makes me go out on the back porch whenever I want a smoke, and that's no fun when the weather's lousy. So I'm trying to quit. Look, I know quitting will be good for me if I can stick to it. And I know it'll save me some money. Besides, I may even get a little peace and quiet!

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YAMATO: Excellent. The reasons you all have given are very important ones. It is good to review them in your mind when you feel the need to smoke. Remind yourself of the many reasons why you decided to quit. You might even write them down and look at them every day. In fact, there's even a wallet card in your User's Guide with space for you to do just that. Whenever you need help to overcome the urge, you can take it out and read what you wrote.

OM: I know one problem I'm going to have. I spend a lot of time at Neary's -- uh, this bar in my neighborhood -- because my buddies hang out there. They all smoke so it's going to be tough for me not to.

YAMATO: Yes, indeed it will. Perhaps you will decide not to go to Neary's for a week or so. But never lose sight of this: you want to give up smoking -- you don't want to give up your lifestyle. So sooner or later you will go back to Neary's. When you do so, it must be in a frame of mind that makes it possible for you to resist the temptation that will be all around you.

OM: How do I do that?

YAMATO: Let us see if we can find an answer. At Neary's, do you have a friend who has given up smoking?

OM: Yeah, Maury. He used to smoke more than anybody there. But I guess he got worried about his health, so he quit. I think he joined some kind of group. He didn't show up at Neary's for a couple of weeks, but he's back to being a regular.

YAMATO: There is your answer. Your friend Maury joined a support group of people who were going through the same difficulties he was. And he avoided Neary's for a while because he knew that the temptation to smoke might be more than he could resist. But after a while he had conquered his addiction well enough to come back and meet with his friends.

OM: Yeah, I guess that might work.

YAMATO: Don't forget, the first few weeks are the hardest, so that's when you should avoid temptation if you can. After that, the mental part of your dependence on cigarettes should be coming under control, and you can resume doing some of the things you may have given up for a while. Soon, you will find yourself taking pride in your ability to be comfortable in situations where others are smoking.

OM: So when I do feel ready to go back to Neary's I have to go with my mind made up not to smoke -- and I have to keep reminding myself of my reasons?

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YAMATO: Exactly. If you tell your friends you're quitting smoking, they'll probably be glad to help support you in your decision, if they think you are sincere.

OW: I think I'll get a lot of support just by looking at the kids. If I remind myself that I'm doing it for them it will be easier than if I was just doing it for myself.

YAMATO: An excellent thought.

YW: With me I guess it's more of a habit than anything else. Pretty often I find myself smoking and I don't even remember reaching for the cigarette and lighting it.

YAMATO: That happens to most smokers. If there aren't any cigarettes around, you won't be able to smoke without thinking about it. That's why most people who want to quit throw away their cigarettes, lighters and ashtrays.

YW: Well, actually I kind of like to smoke. I guess it gives me pleasure, even though it makes my clothes smell.

YAMATO: That is the greatest hurdle to overcome. Smokers get pleasure out of smoking. Not out of every cigarette -- many of them are just from habit. But that first cigarette in the morning is satisfying. And a cigarette with coffee or after a meal is pleasurable for many people. Perhaps the best way to deal with this is to find a substitute pleasure that works for you. Find something to do that is pleasant and that doesn't go well with smoking.

YM: I smoke when I get nervous. Is there anything I can do about that?

YAMATO: Yes, there are techniques you can use to help you relax. For example, breathing.

STUDENTS: Huh? What? Hey, I do that all the time.

YAMATO: I thought that would surprise you. I am not talking about ordinary breathing -the kind we do without thinking about it. I am talking about deep, relaxing breathing -breathing upon which you concentrate all your attention. Perhaps, young lady, you will assist me in demonstrating.

YW: But I don't know anything about that.

YAMATO: That doesn't matter. It's really quite simple. The first thing to do is to sit up straight, but without straining yourself.

YW: Like this?

YAMATO: Yes, but you must relax. Try letting your arms dangle loosely. Shake them a bit to relax the muscles. Make sure your

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leg and back muscles are relaxed too. Move your head around a little to relax your neck. How does that feel?

YW: Pretty good.

YAMATO: Fine. Now, breathe out and then take a slow breath as deeply as you can.

YW: (Exhales. Inhales very deeply.)

YAMATO: Now, hold that breath for a few seconds. Then let it all out slowly. Wait a second and take another deep breath.

YW: (Breathes.)

YAMATO: How does that feel?

YW: Gee. I never knew you could get such a feeling from just breathing.

YAMATO: It is amazing, is it not? Now, to assure that deep breathing truly relaxes you, close your eyes and picture a scene that you find very pleasurable and soothing.

YW: Like walking on the beach?

YAMATO: If that is the scene that makes you feel good, yes.

YM: I'll go along with that. Except I like to do my walking in the woods.

YAMATO: Now, let's all try it. Sit straight but relaxed. Take slow, deep breaths, and think of something that makes you feel at ease.

(Students shift around, shake, breathe a few times.)

OM: Man, I never knew I could get such a kick out of breathing.

OW: Me, too.

YAMATO: That is one of the keys to helping you resist smoking at those critical times. Find something to do that occupies your mind and your body fully. This can help you not think about smoking. Your routine may be as simple as this breathing exercise, but the important thing is to find some easy activity that's right for you.

YM: Boy, that's great. Anything else to help us resist temptation?

YAMATO: Basically, anything that helps you relax. As I said at the start of the class, soothing and peaceful music is a great aid to relaxation. If you're at home and feel the need for a smoke, try putting on some soft music. Sit in a comfortable

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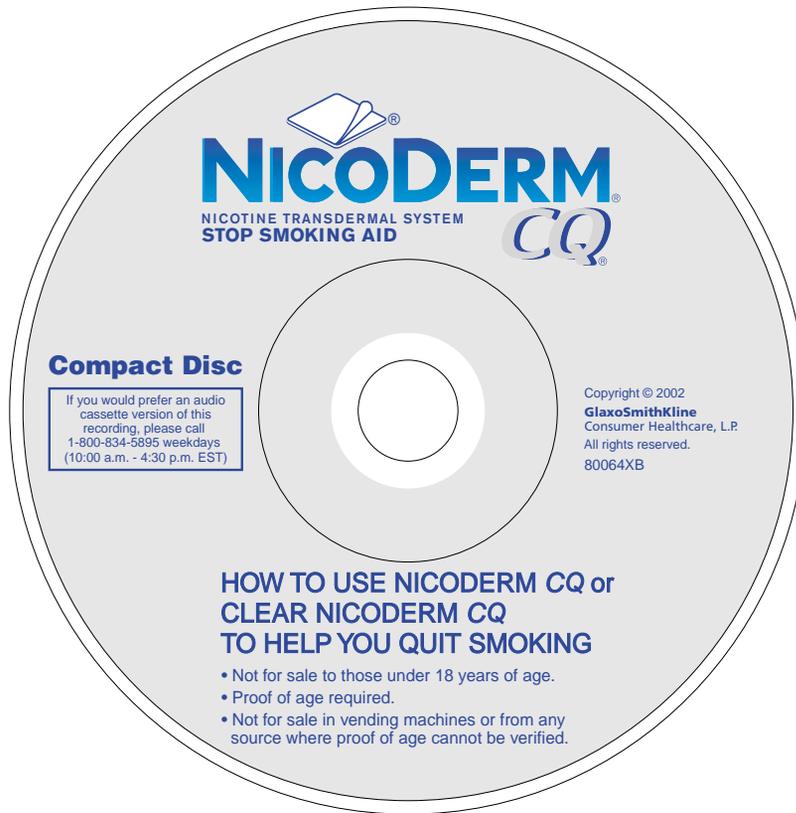
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chair, relax your muscles, breathe deeply and just let yourself float.

You are beginning a process that will not be easy. But if you use the NicoDerm CQ patch properly, as it is explained in the User's Guide, and if you remember these tips to help you get past the mental hurdles, you will greatly increase your chances for success.

Now, we're going to spend the rest of the period just practicing muscle relaxation, deep breathing and calm, soothing mental pictures. Make yourselves comfortable and I will put on some music to help you put all thought of smoking out of your minds. I'm sure you will enjoy it.

(Music up. Plays to end of CD.)



NicoDerm Clear and Opaque CD Label

VARNISH K/O



Compact Disc

**HOW TO USE NICODERM CQ or
CLEAR NICODERM CQ
TO HELP YOU QUIT SMOKING**

- Not for sale to those under 18 years of age.
- Proof of age required.
- Not for sale in vending machines or from any source where proof of age cannot be verified.

If you would prefer an audio cassette version of this recording, please call 1-800-834-5895 weekdays (10:00 a.m. - 4:30 p.m. EST)

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50065355



Compact Disc

**HOW TO USE NICODERM CQ or
CLEAR NICODERM CQ
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50065355

VARNISH K/O

NicoDerm Clear and Opaque CD Sleeve, Front and Back

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-165/S-020

LABELING REVIEWS

**Division of OTC Drug Products
Labeling Review**

NDA # 20-165/SLR-020

Drug Product: Clear NicoDerm CQ (nicotine transdermal system);
Opaque NicoDerm CQ (nicotine transdermal system)

Submission Date: February 13, 2002

Stamp Date: February 14, 2002

Type of Submission: Special Supplement – Changes Being Effected

Sponsor: GlaxoSmithKline

of Stock Keeping Units in Submission: 7

Review Date: July 26, 2002

Reviewer: Mary S. Robinson, HFD-560

Background

Reference is made to a letter dated August 17, 2001, in which the agency requested that the sponsor replace their current pregnancy warning with the following warning:

If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

The sponsor states that three other minor editorial changes have been made to the user's guide labeling. Otherwise, no text has been added or deleted in each of the three changes (see reviewer recommendations, below), but simply moved to a different location in the user's guide.

This review is based on the February 13, 2002 submission of NDA 20-165/SLR-020, received and filed February 14, 2002 by FDA. This submission (Special Supplement – Changes Being Effected) contains full color draft printed labeling for NicoDerm CQ clear and NicoDerm CQ Opaque (nicotine transdermal system) for the Step 1 (21 mg), Step 2 (14 mg), and Step 3 (7 mg) 14 patches cartons and the NicoDerm CQ Opaque Step 1 (21 mg) 7 patches; labeling for the pouch, user's guide and compact disc transcript. Unless otherwise noted, the reviewer's comments and recommendations refer to the labeling, which is essentially the same, for both the NicoDerm CQ Clear and NicoDerm CQ Opaque drug products.

Reviewer's Recommendations

1. The sponsor needs to be informed that:
 - (a) final printed labeling for all marketed SKU's needs to be submitted.
 - (b) on the end flap of all the cartons (see Attachment 1, pages 10, 14, 18, 25, 29, and 33). an apostrophe should be inserted in the word "family's" in the sentence "For your family's protection, NicoDerm CQ patches are supplied in child resistant pouches."

2. The sponsor can be informed that the changes listed below are acceptable.
 - (a) The pregnancy breast-feeding warning has been incorporated in the drug facts labeling as the first warning under the heading "Warnings" on the carton, the user's guide and the compact disc transcript.

3. The sponsor made the following changes in the user's guide:
 - (a) The stickers, which are included in the user's guide, have been moved from the center of the guide to inside the front cover.
 - (b) The inside front cover text of the user's guide has been moved to the inside back cover
 - (c) The Committed Quitters Enrollment form, which was previously supplied as a separate leaflet, has been inserted in the middle of the user's guide in the place previously held by the stickers.

These changes are acceptable.

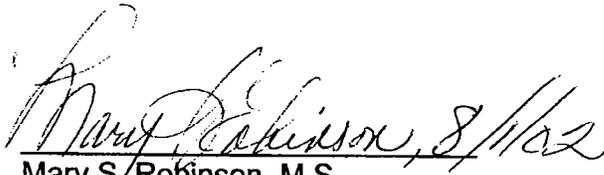
4. Modifications from NDA 20-165/S-019 (August 20, 2001) carton labeling have been made as follows:

Principal Display Panel (PDP) (see Attachment 1, pages 8, 12, 16, 20, 23, 27, and 31)

- (a) The American Cancer Society icon is moved from the top right side to the top left side. The statement " partners in helping you quit" is deleted from the icon.
- (b) A "TIPS" icon with a CD symbol has been added to the top right of the PDP.
- (c) The graphic design box indicating which step the drug product is to be used for has been highlighted and modified to include the phrase "1 WEEK KIT" or "2 WEEK KIT," as appropriate.
- (d) The phrase "1 WEEK KIT" or "2 WEEK KIT," as appropriate, is deleted from the bottom right of the carton.
- (e) Two boxes each with the word "STEP" and a number have been added to the PDP to indicate that the drug product is part of a 3 STEP program.
- (f) The "FREE PERSONALIZED" icon has been moved from the bottom right of the PDP to the top flap of the carton.

Back Panel (see Attachment 1, pages 9, 13, 17, 21, 28, and 32)
(g) "Drug Facts" has been divided into two columns.

These changes are acceptable.

A handwritten signature in cursive script, appearing to read "Mary S. Robinson, 8/1/02".

Mary S. Robinson, M.S.
Regulatory Review Chemist, HFD-560

A handwritten signature in cursive script, appearing to read "Helen Cothran 8/1/02".

Helen Cothran, B.S.
Team Leader, HFD-560

cc: NDA 20-165/S-019

HFD-170: Jani

HFD-560: Ganley/Katz/Cothran/Hu/Robinson/Abraham

HFD-560: Division File

R/D: MRobinson

F/T: MRobinson

DocID: C:\Data\Nicotine CQ\NDA 20165-CBE 2-13-02.doc

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this page is the manifestation of the electronic signature.**

/s/

Mary Robinson
8/6/02 10:35:00 AM
INTERDISCIPLINARY

Helen Cothran
8/6/02 10:48:17 AM
INTERDISCIPLINARY

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-165/S-020

CORRESPONDENCE



GlaxoSmithKline

NDA 20-165

February 13, 2002

Charles Ganley, M.D.
Director

Division of Over the Counter Drug Products
Office of Drug Evaluation V, HFD-560
Center for Drug Evaluation and Research
9201 Corporate Blvd
Rockville, MD 20850

Consumer Healthcare
1500 Littleton Road
Parsippany, NJ
07054-3884

Tel. 973 889 2100
Fax. 973 889 2390
www.gsk.com

**RE: Special Supplement - Changes Being Effected
NicoDerm CQ (nicotine transdermal system)**

Dear Dr. Ganley,

Reference is made to correspondence from CDER, which was received by GlaxoSmithKline Consumer Healthcare (GSKCH) on August 17, 2001, in which a request was made to alter the approved labeling for the above referenced NDA by replacing the current pregnancy warning with the one provided in the August 17 correspondence. All finished product labeling including the audio, cartons and user's guides have been changed to reflect the requested new pregnancy warning.

Three other minor editorial changes to the labeling are also including in this submission. The intention of GSKCH was to notify the agency of these minor changes via annual report but takes the opportunity to do so at this time due to the subject of this submission. No text has been added or deleted in each of the three changes but simply moved to a different location in the user's guide. The three changes are as follows:

1. The stickers, which are included in the user's guide, have been moved from the center of the guide to inside the front cover.
2. The inside front cover text of the user's guide has been moved to the inside back cover.
3. The Committed Quitters Enrollment form, which was previously a supplied as a separate leaflet, has been inserted in the middle of the user's guide in the place previously held by the stickers.

In accordance with the request of the correspondence, GSKCH hereby submits the labeling in electronic format as presented in the guidance for industry *Providing Regulatory Submissions in Electronic Format – NDA* (January 1999).

The CDROM has been confirmed as virus free using McAfee VirusScan software (version 4.0.2, virus definition version 4.0.4148 – updated 7/18/2001) from Network Associates Incorporated. If there are any questions or additional information is required pertaining to this submission, please contact the undersigned at (973) 889-2173 by phone or by fax at (973) 889-2501.

Sincerely,



Parker J. Holmes
Manager, Regulatory Affairs
GlaxoSmithKline Consumer Healthcare

cc: Elaine Abraham (desk copy)



NDA 20-165 / S-020

CBE-0 SUPPLEMENT

GlaxoSmithKline Consumer Healthcare
Attention: Parker J. Holmes
Manager, Regulatory Affairs
1500 Littleton Rd.
Parsippany, NJ 07054-3884

Dear Mr. Holmes:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: NicoDerm CQ (21 mg, 14 mg, 7 mg nicotine transdermal system)
NDA Number: 20-165
Supplement number: S-020
Date of supplement: February 13, 2002
Date of receipt: February 14, 2002

This supplemental application, submitted as a "Supplement - Changes Being Effected" supplement, proposes revised final printed labeling which incorporates the current pregnancy/breast-feeding warning.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on April 15, 2002, in accordance with 21 CFR.314.101(a).

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplement should be addressed as follows:

U.S. Postal Service and Courier/Overnight Mail:

Center for Drug Evaluation and Research
Division of Over-the-Counter Drug Products, HFD-560
Attention: Division Document Room
9201 Corporate Blvd.
Rockville, Maryland 20850-3202

If you have any questions, call Elaine Abraham, R.Ph., Regulatory Health Project Manager, at (301) 827-2293.

Sincerely,

{See appended electronic signature page}

David Hilfiker
Chief, Project Management Staff
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

David Hilfiker
3/15/02 12:03:17 PM