Reference ID: 4150911

NO COPY AREA

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Lot:

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THEFT SURVEILLANCE TAG AREA

PLACE ANTI-THEFT STICKER HERE

Drug Facts (continued)

Other information

- **each piece contains:** calcium 94 mg, sodium 11 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Inactive ingredients

acacia, acesulfame potassium, carnauba wax, edible ink, flavors, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium bicarbonate, sodium carbonate, sucralose, titanium dioxide, xylitol

Questions or comments?

call toll-free **1-800-419-4766**

Drug Facts

Active ingredient (in each chewing piece)	Purpose
Nicotine polacrilex (equal to 2 mg nicotine)	Stop smoking aid

Use

- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

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.

Ask a doctor before use if you have
- a sodium-restricted diet
- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase blood pressure.
- stomach ulcer or diabetes
- history of seizures

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.

Stop use and ask a doctor if
- mouth, teeth or jaw problems occur
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away.

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 important information
- begin using the gum on your quit day
- **if you smoke your first cigarette within 30 minutes of waking up,** use 4 mg nicotine gum
- **if you smoke your first cigarette more than 30 minutes after waking up,** use 2 mg nicotine gum according to the following 12 week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours

- nicotine gum is a medicine and must be used a certain way to get the best results
- chew the gum slowly until it tingles. Then park it between your cheek and gum. When the tingle is gone, begin chewing again, until the tingle returns.
- repeat this process until most of the tingle is gone (about 30 minutes)
- do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece
- to improve your chances of quitting, use at least 9 pieces per day for the first 6 weeks
- if you experience strong or frequent cravings, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you hiccups, heartburn, nausea or other side effects.
- do not use more than 24 pieces a day
- it is important to complete treatment. If you feel you need to use the gum for a longer period to keep from smoking, talk to your health care provider.

EAS Tagged

0 0000-0000-00 0

17-001CHFS

Nicorette®

Spearmint Burst

with a hint of chamomile

- **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**

This product is protected in sealed blisters. **Do not use if individual blisters or printed backings are broken, open, or torn.**

Distributed by
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Made in Sweden

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For more information and for a FREE individualized stop smoking program, please visit www.Nicorette.com or see inside for more details.

17-001CHFS

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OPEN HERE

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. **Use Enough** - Chew **at least 9 pieces** of **Nicorette®** gum per day during the first six weeks.
3. **Use Long Enough** - Use **Nicorette®** gum for the full 12 weeks.
4. **Use with a support program** as directed in the enclosed User's Guide.

To remove the gum, tear off single unit.

Peel off backing, starting at corner with loose edge.

Push gum through foil.

100 PIECES, 2 mg EACH

NDC 0135-0532-02

NEW FLAVOR

gsk

Nicorette®

nicotine polacrilex gum, 2 mg · stop smoking aid

Gum

Coated FOR BOLD FLAVOR

Spearmint Burst

with a hint of chamomile

2 mg

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP.

If you smoke your first cigarette **WITHIN 30 MINUTES** of waking up, use Nicorette® 4 mg Gum

100 PIECES, 2 mg EACH

GSK Regulatory Spec Box — Verified Date: 2/20/17

Drug Facts Info

Drug Facts (Title)	Font Name: Helvetica Neue 76 Bold Italic	14 point type
Drug Facts (continued)	Font Name: Helvetica Neue 76 Bold Italic/Helvetica Neue 57 Condensed	8.1 point type
Headings	Font Name: Helvetica Neue 76 Bold Italic	8 point type
Subheading	Font Name: Helvetica Neue 77 Bold Condensed	6.5 point type
Body text	Font Name: Helvetica Neue 57 Condensed/ Helvetica Neue 77 Bold Condensed	6.5 point type
Bullets	Font Name: Helvetica Neue 55 Roman	5 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		N/A
Spacing of the hair lines from edge of box – i.e. Minimum of 2 spaces either side of Drug Fact Box		Yes

Tracking	0	Horizontal Scale:	100%
Leading (Minimum space in body copy of Drug Facts)	6.75 pt.	Maximum Characters/Inch:	32
Barlines	1 pt.	Hairlines	0.5 pt.

Primary Display Panel Info

Font size of Net Wt/Contents (Smallest character height in inches)	0.1413 in.
PDP dimensions (in square inches)	23.02 sq. in.
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")	V 16.11 pt. H N/A
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")	V 63.56 pt. H N/A
Ratio of Statement of Identity to Logo/Largest Copy on PDP Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)	V 25% H N/A

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PLACE ANTI-THEFT STICKER HERE

THEFT SURVEILLANCE TAG AREA

Drug Facts (continued)

Other information
- **each piece contains:** calcium 94 mg, sodium 11 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Inactive ingredients
acacia, acesulfame potassium, carnauba wax, edible ink, flavors, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium bicarbonate, sodium carbonate, sucralose, titanium dioxide, xylitol

Questions or comments? call toll-free **1-800-419-4766**

Drug Facts

Active ingredient (in each chewing piece) ***Purpose***
Nicotine polacrilex (equal to 2 mg nicotine) ..... Stop smoking aid

Use • reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

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.

Ask a doctor before use if you have
- a sodium-restricted diet
- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase blood pressure.
- stomach ulcer or diabetes
- history of seizures

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.

Stop use and ask a doctor if
- mouth, teeth or jaw problems occur
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away.

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 important information
- begin using the gum on your quit day
- **if you smoke your first cigarette within 30 minutes of waking up,** use 4 mg nicotine gum
- **if you smoke your first cigarette more than 30 minutes after waking up,** use 2 mg nicotine gum according to the following 12 week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours

- nicotine gum is a medicine and must be used a certain way to get the best results
- chew the gum slowly until it tingles. Then park it between your cheek and gum. When the tingle is gone, begin chewing again, until the tingle returns.
- repeat this process until most of the tingle is gone (about 30 minutes)
- do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece
- to improve your chances of quitting, use at least 9 pieces per day for the first 6 weeks
- if you experience strong or frequent cravings, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you hiccups, heartburn, nausea or other side effects.
- do not use more than 24 pieces a day
- it is important to complete treatment. If you feel you need to use the gum for a longer period to keep from smoking, talk to your health care provider.

EAS Tagged

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Nicorette®

Spearmint Burst
with a hint of chamomile

- **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**

This product is protected in sealed blisters.
Do not use if individual blisters or printed backings are broken, open, or torn.

Distributed by
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Warren, NJ 07059
Made in Sweden

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17-002CHFS

17-002CHFS

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NO VARNISH AREAS

OPEN HERE

TO INCREASE YOUR SUCCESS IN QUITTING:
1. You must be motivated to quit.
2. **Use Enough** - Chew **at least 9 pieces** of **Nicorette**® gum per day during the first six weeks.
3. **Use Long Enough** - Use **Nicorette**® gum for the full 12 weeks.
4. **Use with a support program** as directed in the enclosed User's Guide.

To remove the gum, tear off single unit.

Peel off backing, starting at corner with loose edge.

Push gum through foil.

160 PIECES, 2 mg EACH

NDC 0135-0532-03

NEW FLAVOR

gsk

Nicorette®

nicotine polacrilex gum, 2 mg · stop smoking aid

Gum

Coated
FOR BOLD FLAVOR

Spearmint Burst
with a hint of chamomile

160 PIECES, 2 mg EACH

2 mg

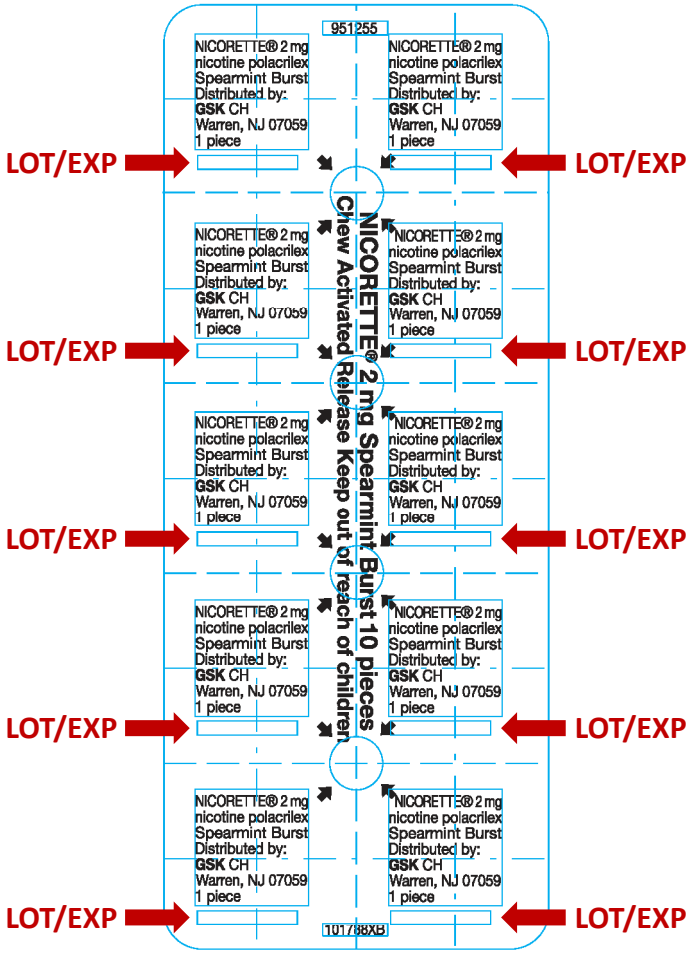
FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP.
If you smoke your first cigarette **WITHIN 30 MINUTES** of waking up, use Nicorette® 4 mg Gum

Nicorette®
Spearmint Burst
with a hint of chamomile

GSK Regulatory Spec Box			Verified Date: 01.27.17
Drug Facts Info			
Drug Facts (Title)	Font Name: Helvetica Neue 76 Bold Italic		14.0 point type
Drug Facts (continued)	Font Name: Helvetica Neue 76 Bold Italic/Helvetica Neue 57 Condensed		8.10 point type
Headings	Font Name: Helvetica Neue 76 Bold Italic		8.00 point type
Subheadings	Font Name: Helvetica Neue 77 Bold		6.50 point type
Body text	Font Name: Helvetica Neue 77 Bold Condense/Helvetica Neue 57 Condensed		6.50 point type
Bullets	Font Name: Helvetica Neue 55 Roman		5.00 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems			Yes
Spacing of the hair lines from edge of box – i.e. Minimum of 2 spaces either side of Drug Fact Box			Yes
Tracking	0	Horizontal Scale:	100%
Leading (Minimum space in body copy of Drug Facts)	6.75 pt.	Maximum Characters/Inch:	30
Barlines	1.00 pt.	Hairlines	0.50 pt.
Primary Display Panel Info			
Font size of Net Wt/Contents (Smallest character height in inches)			0.1413 in.
PDP dimensions (in square inches)			23.02 sq. in.
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")			V 16.11 pt. H N/A
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")			V 63.56 pt. H N/A
Ratio of Statement of Identity to Logo/Largest Copy on PDP Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)			V 25% H N/A

Reference ID: 4150911

NDA 018612: Nicorette Gum, Spearmint Burst, 2 mg



Reference ID: 4150911

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Lot:

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THEFT SURVEILLANCE TAG AREA

PLACE ANTI-THEFT STICKER HERE

Drug Facts (continued)

Other information

- **each piece contains:** calcium 94 mg, sodium 13 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Inactive ingredients

acacia, acesulfame potassium, carnauba wax, D&C yellow #10 Al. lake, edible ink, flavors, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium carbonate, sucralose, titanium dioxide, xylitol

Questions or comments?

call toll-free **1-800-419-4766**

Drug Facts

Active ingredient (in each chewing piece)	Purpose
Nicotine polacrilex (equal to 4 mg nicotine)	Stop smoking aid

Use • reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

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.

Ask a doctor before use if you have
- a sodium-restricted diet
- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase blood pressure.
- stomach ulcer or diabetes
- history of seizures

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.

Stop use and ask a doctor if
- mouth, teeth or jaw problems occur
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away.

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 important information
- begin using the gum on your quit day
- **if you smoke your first cigarette more than 30 minutes after waking up,** use 2 mg nicotine gum
- **if you smoke your first cigarette within 30 minutes of waking up,** use 4 mg nicotine gum according to the following 12 week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours

- nicotine gum is a medicine and must be used a certain way to get the best results
- chew the gum slowly until it tingles. Then park it between your cheek and gum. When the tingle is gone, begin chewing again, until the tingle returns.
- repeat this process until most of the tingle is gone (about 30 minutes)
- do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece
- to improve your chances of quitting, use at least 9 pieces per day for the first 6 weeks
- if you experience strong or frequent cravings, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you hiccups, heartburn, nausea or other side effects.
- do not use more than 24 pieces a day
- it is important to complete treatment. If you feel you need to use the gum for a longer period to keep from smoking, talk to your health care provider.

EAS Tagged

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17-003CHFS

Nicorette®

Spearmint Burst

with a hint of chamomile

- **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**

This product is protected in sealed blisters. **Do not use if individual blisters or printed backings are broken, open, or torn.**

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For more information and for a FREE individualized stop smoking program, please visit www.Nicorette.com or see inside for more details.

17-003CHFS

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Nicorette®

Spearmint Burst

with a hint of chamomile

OPEN HERE

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. **Use Enough** - Chew **at least 9 pieces** of **Nicorette®** gum per day during the first six weeks.
3. **Use Long Enough** - Use **Nicorette®** gum for the full 12 weeks.
4. **Use with a support program** as directed in the enclosed User's Guide.

To remove the gum, tear off single unit.

Peel off backing, starting at corner with loose edge.

Push gum through foil.

100 PIECES, 4 mg EACH

NDC 0135-0533-02

NEW FLAVOR

gsk

Nicorette®

nicotine polacrilex gum, 4 mg · stop smoking aid

Gum

Coated FOR BOLD FLAVOR

Spearmint Burst

with a hint of chamomile

100 PIECES, 4 mg EACH

4 mg

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP.

If you smoke your first cigarette **MORE THAN 30 MINUTES** after waking up, use Nicorette® 2 mg Gum

GSK Regulatory Spec Box — Verified Date: 2/20/17

Drug Facts Info

Drug Facts (Title)	Font Name: Helvetica Neue 76 Bold Italic	14 point type
Drug Facts (continued)	Font Name: Helvetica Neue 76 Bold Italic/Helvetica Neue 57 Condensed	8.1 point type
Headings	Font Name: Helvetica Neue 76 Bold Italic	8 point type
Subheading	Font Name: Helvetica Neue 77 Bold Condensed	6.5 point type
Body text	Font Name: Helvetica Neue 57 Condensed/ Helvetica Neue 77 Bold Condensed	6.5 point type
Bullets	Font Name: Helvetica Neue 55 Roman	5 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		N/A
Spacing of the hair lines from edge of box – i.e. Minimum of 2 spaces either side of Drug Fact Box		Yes

Tracking	0	Horizontal Scale:	100%
Leading (Minimum space in body copy of Drug Facts)	6.75 pt.	Maximum Characters/Inch:	32
Barlines	1 pt.	Hairlines	0.5 pt.

Primary Display Panel Info

Font size of Net Wt/Contents (Smallest character height in inches)	0.1413 in.
PDP dimensions (in square inches)	23.02 sq. in.
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")	V 16.11 pt. H N/A
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")	V 63.56 pt. H N/A
Ratio of Statement of Identity to Logo/Largest Copy on PDP Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)	V 25% H N/A

NO COPY AREA

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Lot:

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PLACE ANTI-THEFT STICKER HERE

THEFT SURVEILLANCE TAG AREA

Drug Facts (continued)

Other information

- **each piece contains:** calcium 94 mg, sodium 13 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Inactive ingredients

acacia, acesulfame potassium, carnauba wax, D&C yellow #10 Al. lake, edible ink, flavors, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium carbonate, sucralose, titanium dioxide, xylitol

Questions or comments? call toll-free **1-800-419-4766**

Drug Facts

Active ingredient (in each chewing piece) ***Purpose***

Nicotine polacrilex (equal to 4 mg nicotine) ..... Stop smoking aid

Use • reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

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.

Ask a doctor before use if you have

- a sodium-restricted diet
- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase blood pressure.
- stomach ulcer or diabetes
- history of seizures

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.

Stop use and ask a doctor if

- mouth, teeth or jaw problems occur
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away.

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 important information
- begin using the gum on your quit day
- **if you smoke your first cigarette more than 30 minutes after waking up,** use 2 mg nicotine gum
- **if you smoke your first cigarette within 30 minutes of waking up,** use 4 mg nicotine gum according to the following 12 week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours

- nicotine gum is a medicine and must be used a certain way to get the best results
- chew the gum slowly until it tingles. Then park it between your cheek and gum. When the tingle is gone, begin chewing again, until the tingle returns.
- repeat this process until most of the tingle is gone (about 30 minutes)
- do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece
- to improve your chances of quitting, use at least 9 pieces per day for the first 6 weeks
- if you experience strong or frequent cravings, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you hiccups, heartburn, nausea or other side effects.
- do not use more than 24 pieces a day
- it is important to complete treatment. If you feel you need to use the gum for a longer period to keep from smoking, talk to your health care provider.

EAS Tagged

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Nicorette®

Spearmint Burst

with a hint of chamomile

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For more information and for a FREE individualized stop smoking program, please visit www.Nicorette.com or see inside for more details.

17-004CHFS

17-004CHFS

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NO VARNISH AREAS

Nicorette®

Spearmint Burst

with a hint of chamomile

OPEN HERE

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. **Use Enough** - Chew **at least 9 pieces** of **Nicorette®** gum per day during the first six weeks.
3. **Use Long Enough** - Use **Nicorette®** gum for the full 12 weeks.
4. **Use with a support program** as described in the enclosed User's Guide.

To remove the gum, tear off single unit.

Peel off backing, starting at corner with loose edge.

Push gum through foil.

160 PIECES, 4 mg EACH

NDC 0135-0355-03

NEW FLAVOR

gsk

Nicorette®

nicotine polacrilex gum, 4 mg · stop smoking aid

Gum

Coated

FOR BOLD FLAVOR

Spearmint Burst

with a hint of chamomile

4 mg

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP.

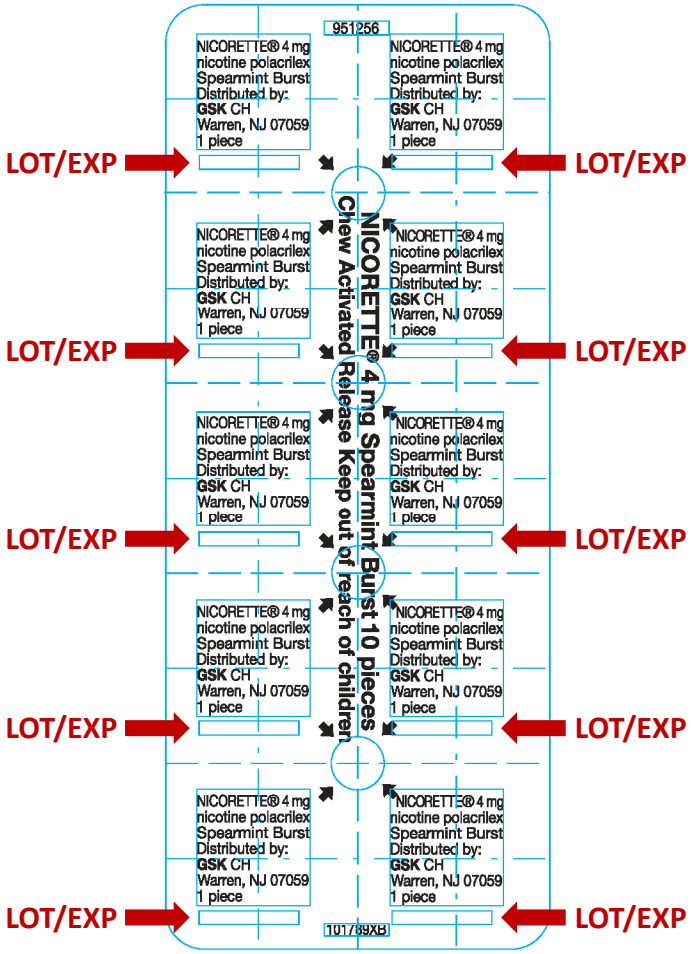
If you smoke your first cigarette MORE THAN 30 MINUTES after waking up, use Nicorette® 2 mg Gum

160 PIECES, 4 mg EACH

GSK Regulatory Spec Box			Verified Date: 01.27.17
Drug Facts Info			
Drug Facts (Title)	Font Name: Helvetica Neue 76 Bold Italic		14.0 point type
Drug Facts (continued)	Font Name: Helvetica Neue 76 Bold Italic/Helvetica Neue 57 Condensed		8.10 point type
Headings	Font Name: Helvetica Neue 76 Bold Italic		8.00 point type
Subheadings	Font Name: Helvetica Neue 77 Bold		6.50 point type
Body text	Font Name: Helvetica Neue 77 Bold Condense/Helvetica Neue 57 Condensed		6.50 point type
Bullets	Font Name: Helvetica Neue 55 Roman		5.00 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems			Yes
Spacing of the hair lines from edge of box – i.e. Minimum of 2 spaces either side of Drug Fact Box			Yes
Tracking	0	Horizontal Scale:	99-100%
Leading (Minimum space in body copy of Drug Facts)	6.75 pt.	Maximum Characters/Inch:	30
Barlines	1.00 pt.	Hairlines	0.50 pt.
Primary Display Panel Info			
Font size of Net Wt/Contents (Smallest character height in inches)			0.1413 in.
PDP dimensions (in square inches)			23.02 sq. in.
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")			V 16.11 pt. H N/A
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")			V 63.56 pt. H N/A
Ratio of Statement of Identity to Logo/Largest Copy on PDP Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)			V 25% H N/A

Reference ID: 4150911

NDA 020066: Nicorette Gum, Spearmint Burst, 4 mg



FRONT VIEW

HOW TO USE NICORETTE® GUM TO HELP YOU QUIT SMOKING.

Nicorette®

gsk

nicotine polacrilex gum
2 mg and 4 mg User's Guide

Gum

KEYS TO SUCCESS.

1) You must really want to quit smoking for **Nicorette**® Gum to help you.
2) You can greatly increase your chances for success by using at least 9 to 12 pieces every day when you start using **Nicorette** Gum. See chart on back side of User's Guide.
3) You should continue to use **Nicorette** Gum as explained in this User's Guide for 12 full weeks. If you feel you need to use **Nicorette** Gum for a longer period to keep from smoking, talk to your health care provider.
4) **Nicorette** Gum works best when used together with a support program — See information below for instructions on enrollment in the Committed Quitters® Individualized Stop Smoking Program.
5) If you have trouble using **Nicorette** Gum, ask your doctor or pharmacist or call GlaxoSmithKline at 1-800-419-4766.

SO YOU DECIDED TO QUIT.

Congratulations. Your decision to stop smoking is an important one. That's why you've made the right choice in choosing **Nicorette** Gum.

Your own chances of quitting smoking depend on how much you want to quit, how strongly you are addicted to tobacco, and how closely you follow a quitting program like the one that comes with **Nicorette** Gum.

QUITTING SMOKING IS HARD!

If you've tried to quit before and haven't succeeded, don't be discouraged! Quitting isn't easy. It takes time, and most people try a few times before they are successful. The important thing is to try again until you succeed. This User's Guide will give you support as you become a non-smoker. It will answer common questions about **Nicorette** Gum and give tips to help you stop smoking, and should be referred to often.

WHERE TO GET HELP.

You are more likely to stop smoking by using **Nicorette** Gum 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 of this User's Guide.

If you find you cannot stop smoking or if you start smoking again after using **Nicorette** Gum, 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 **Nicorette** Gum 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 on the bottom left 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.

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 **Nicorette** Gum will lessen your body's physical addiction to 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.

Ask a doctor before use if you have
- a sodium-restricted diet
- 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.
- stomach ulcer or diabetes
- history of seizures

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.

Stop use and ask a doctor if
- mouth, teeth or jaw problems occur
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away.

LET'S GET STARTED.

Becoming a non-smoker starts today. First, check that you bought the right starting dose. **If you smoke your first cigarette within 30 minutes of waking up,** use 4 mg nicotine gum. **If you smoke your first cigarette more than 30 minutes after waking up,** use 2 mg nicotine gum. Next, read through the entire User's Guide carefully. Then, set your personalized quitting schedule. Take out a calendar that you can use to track your progress, and identify four dates, using the reminders on the bottom left of this User's Guide:

STEP 1 (Weeks 1-6).
Your quit date (and the day you'll start using Nicorette® Gum).
Choose your quit date (it should be soon). This is the day you will begin using **Nicorette** Gum to satisfy your cravings for nicotine. For the first six weeks, you'll use a piece of **Nicorette** Gum every hour or two. Be sure to read the HOW TO USE NICORETTE GUM section. Place the Step 1 reminder on this date.

STEP 2 (Weeks 7-9).
The day you'll start reducing your use of Nicorette® Gum.
After six weeks, you'll begin gradually reducing your **Nicorette** Gum usage to one piece every two to four hours. Place the Step 2 reminder on this date (the first day of week seven).

STEP 3 (Weeks 10-12).
The day you'll further reduce your use of Nicorette® Gum.
Nine weeks after you begin using **Nicorette** Gum, you will further reduce your nicotine intake by using one piece every four to eight hours. Place the Step 3 reminder on this date (the first day of week ten). For the next three weeks, you'll use a piece of **Nicorette** Gum every four to eight hours.

End of treatment:
The day you'll complete Nicorette® Gum therapy.
Identify the date thirteen weeks after the date you chose in Step 1, and place the "EX-SMOKER" reminder on your calendar.

PLAN AHEAD.

Because smoking is an addiction, it is not easy to stop. After you've given up cigarettes, you will still have a strong urge to smoke. Plan ahead NOW for these times, so you're not defeated in a moment of weakness. The following tips may help:
- Keep the phone numbers of supportive friends and family members handy.
- Keep a record of your quitting process. Track the number of **Nicorette** Gum pieces you use each day, and whether you feel a craving for cigarettes. In the event that you slip, immediately stop smoking and resume your quit attempt with the **Nicorette** Gum program.
- Put together an Emergency Kit that includes items that will help take your mind off occasional urges to smoke. Include cinnamon gum or lemon drops to suck on, a relaxing CD, 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 NICORETTE® GUM WORKS.

Nicorette Gum's sugar-free chewing pieces provide nicotine to your system – they work as a temporary aid to help you quit smoking by reducing nicotine withdrawal symptoms. **Nicorette** Gum 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. Because **Nicorette** Gum 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 NICORETTE® GUM.

If you are under 18 years of age, ask a doctor before use. Before you can use **Nicorette** Gum correctly, you have to practice! That sounds silly, but it isn't. **Nicorette Gum isn't like ordinary chewing gum.** It's a medicine, and must be chewed a certain way to work right. Chewed like ordinary gum, **Nicorette** Gum won't work well and can cause side effects.

PLACE THESE REMINDERS ON YOUR CALENDAR:

AT THE BEGINNING OF WEEK #1 (QUIT DATE) — STEP 1: 1 piece every 1 to 2 hours

AT THE BEGINNING OF WEEK #7 — STEP 2: 1 piece every 2 to 4 hours

AT THE BEGINNING OF WEEK #10 — STEP 3: 1 piece every 4 to 8 hours

12 WEEKS AFTER QUIT DATE — EX-SMOKER

A Personal Invitation to Join

brought to you by

Nicorette® Gum

FREE INDIVIDUALIZED STOP SMOKING PROGRAM COMMITTED QUITTERS®

ENROLL NOW!

Having a Plan Will Help You Quit

Nicorette Committed Quitters® is a FREE custom-tailored plan to help you break your psychological addiction to smoking — while NICORETTE® GUM fights the physical addiction. To get your plan, call toll free 1-800-770-0708 or visit us on the Web at www.committedquitters.com.

WHEN YOU CALL:
You will be asked a few questions to understand YOU and YOUR specific needs.

AFTER YOU CALL:
In a few days, you will receive your custom-tailored stop smoking plan. You will continue to receive personal, custom-tailored support — six times during the next twelve weeks.

To Enroll Call Now
1-800-770-0708
or enroll online at
www.committedquitters.com

Your Plan Will Contain:

Week 1: 12-week stop smoking plan
Week 2: Newsletter with stories from other successful quitters
Week 3: Motivational postcard
Week 6: More tips on quitting
Week 9: Congratulations Packet
Week 12: Award Certificate

Materials are subject to change.

*The **Committed Quitters**® program is a plan specifically individualized for you.*

Call Between 7 am and 12 Midnight ET or enroll online 24 hours a day. (ONE PLAN PER CUSTOMER)

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WALLET CARD

My most important reasons to quit smoking are:

_____
_____
_____
_____

Nicorette®
nicotine polacrilex gum
2 mg and 4 mg User's Guide
Gum

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BACK VIEW

An overdose can occur if you chew more than one piece of **Nicorette** Gum at the same time, or if you chew many pieces one after another. Read all the following instructions before using **Nicorette** Gum. Refer to them often to make sure you're using **Nicorette** Gum correctly. If you chew too fast, or do not chew correctly, you may get hiccups, heartburn, or other stomach problems. Don't eat or drink for 15 minutes before using **Nicorette** Gum, or while chewing a piece. The effectiveness of **Nicorette** Gum may be reduced by some foods and drinks, such as coffee, juices, wine or soft drinks.

1) Begin using **Nicorette** Gum on your quit day.
2) To reduce craving and other withdrawal symptoms, use **Nicorette** Gum according to the dosage schedule below.
3) Chew each **Nicorette** Gum piece very slowly several times.
4) Stop chewing when you notice a peppery taste, or a slight tingling in your mouth. (This usually happens after about 15 chews, but may vary from person to person.)
5) "PARK" the **Nicorette** Gum piece between your cheek and gum, and leave it there.
6) When the peppery taste or tingle is almost gone (in about a minute), start to chew a few times slowly again. When the taste or tingle returns, stop again.
7) Park the **Nicorette** Gum piece again (in a different place in your mouth).
8) Repeat steps 3 to 7 (chew, chew, park) until most of the nicotine is gone from the **Nicorette** Gum piece (usually happens in about half an hour; the peppery taste or tingle won't return.)
9) Wrap the used **Nicorette** Gum piece in paper and throw away in the trash.

The following chart lists the recommended usage schedule for Nicorette® Gum:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours
DO NOT USE MORE THAN 24 PIECES PER DAY.		

To improve your chances of quitting, use at least 9 pieces of **Nicorette** Gum a day. If you experience strong or frequent cravings, you may use a second piece within the hour.
However, do not continuously use one piece after another, since this may cause you hiccups, heartburn, nausea or other side effects.

HOW TO REDUCE YOUR NICORETTE® GUM USAGE.

The goal of using **Nicorette** Gum is to slowly reduce your dependence on nicotine. The schedule for using **Nicorette** Gum will help you reduce your nicotine craving gradually as you reduce and then stop your use of **Nicorette** Gum. Here are some tips to help you cut back during each step and then stop using **Nicorette** Gum:
- After a while, start chewing each **Nicorette** Gum piece for only 10 to 15 minutes, instead of half an hour. Then, gradually begin to reduce the number of pieces used.
- Or, try chewing each piece for longer than half an hour, but reduce the number of pieces you use each day.
- Substitute ordinary chewing gum for some of the **Nicorette** Gum pieces you would normally use. Increase the number of pieces of ordinary gum as you cut back on the **Nicorette** Gum pieces.
- Check how well you've reduced your daily usage of **Nicorette** Gum in Weeks 10 to 12. You should only be using about 3 to 5 pieces a day. Get ready to stop.

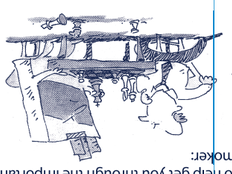
The following tips may help you try to stop using **Nicorette** Gum when you have completed treatment.
- Use the same number of pieces of confectionery gum or mints as you were using **Nicorette** Gum per day. At the times when you have an urge to use **Nicorette** Gum, use a strong flavored gum or mint such as cinnamon or peppermint.
- Reduce the number of pieces of gum or mints you use by one piece per day until you do not need to use any gum or mints.
- Set a stop date.

Talk to your doctor or health care provider if you:
- still feel the need to use **Nicorette** Gum at the end of week 12 to keep from smoking
- start using **Nicorette** Gum again after stopping
- start smoking again

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.
- 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.
- 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.
- Keep **Nicorette** Gum near your bed, so you'll be prepared for any nicotine cravings when you wake up in the morning.
- 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 which 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.
- Laughter helps. Watch or read something funny.

WHAT TO EXPECT.

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 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 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. 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 has not spoiled your efforts! Discard your cigarettes, forgive yourself and try again. If you start smoking again, keep your box of **Nicorette** Gum for your next quit attempt.
If you have taken up regular smoking again, don't be discouraged. Research shows that the best thing you can do is to try again. The important thing is to learn from your last attempt.
- 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 **Nicorette** Gum correctly over the full 12 weeks to reduce your craving for nicotine.
- 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. 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 Nicorette® Gum?
You'll need to prepare yourself for some nicotine withdrawal symptoms. These begin almost immediately after you stop smoking, and are usually at their worst during the first three or four days. Understand that any of the following is possible:
- craving for cigarettes
- anxiety, irritability, restlessness, mood changes, nervousness
- drowsiness
- trouble concentrating
- increased appetite and weight gain
- headaches, muscular pain, constipation, fatigue.

Nicorette Gum can help provide relief from withdrawal symptoms such as irritability and nervousness, as well as the craving for nicotine you used to satisfy by having a cigarette.

2. Is Nicorette® Gum just substituting one form of nicotine for another?
Nicorette Gum does contain nicotine. The purpose of **Nicorette** Gum is to provide you with enough nicotine to help control the physical withdrawal symptoms so you can deal with the mental aspects of quitting. During the 12 week program, you will gradually reduce your nicotine intake by switching to fewer pieces each day.

3. Can I be hurt by using Nicorette® Gum?
For most adults, the amount of nicotine in the gum is less than from smoking. Some people will be sensitive to even this amount of nicotine and should not use this product without advice from their doctor. Check the SOME IMPORTANT WARNINGS section on the front of this User's Guide.
Because **Nicorette** Gum is a gum-based product, chewing it can cause dental fillings to loosen and aggravate other mouth, tooth and jaw problems. **Nicorette** Gum can also cause hiccups, heartburn and other stomach problems especially if chewed too quickly or not chewed correctly.

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.

5. Is Nicorette® Gum more expensive than smoking?
The total cost of **Nicorette** Gum for the twelve week program is about equal to what a person who smokes one and a half packs of cigarettes a day would spend on cigarettes for the same period of time. Also, use of **Nicorette** Gum is only a short-term cost, while the cost of smoking is a long-term cost, because of 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!

Quitting Tips

How To Survive the First Week:

1. Control your physical cravings for nicotine.
Use enough — You can greatly increase your chances for success by using at least 9 to 12 pieces every day when you start using **Nicorette**® Gum.

2. Get rid of all signs that you ever smoked —
ashtrays, matches and, of course, cigarettes.

3. Stay active. Keep busy to take your mind off smoking.

4. Think positive! The first week is the toughest. Remind yourself that it will get easier.

TIPS
- Make sure you tell friends and family members that you quit.
- Use enough Nicorette® Gum — at least 9 to 12 pieces per day.
- Stay active. Keep busy to take your mind off smoking.
- When an urge to smoke strikes, take a few deep breaths and remind yourself how important quitting is to you.

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WEEK ONE

The toughest hurdle — your first week without cigarettes. Your craving for nicotine will be strongest during this first week. To deal with physical withdrawal, use **Nicorette**® Gum properly. Follow the directions on your **Nicorette**® Gum package.

Use this sample of the Stop Smoking Plan to get you through the first week until your materials arrive.

Day	Pieces Chewed	Planning: Plan ahead. Note events here that will tempt you to smoke, and how you will deal with them.
1.		
2.		
3.		
4.		
5.		
6.		
7.		

*Carry this calendar with you.

If you have gone back to smoking, call 1-800-770-0708 to order relapse information.

WALLET CARD

WHERE TO CALL FOR HELP:

American Lung Association 1-800-586-4872

American Cancer Society 1-800-227-2345

American Heart Association 1-800-242-8721