

**Drug Facts (continued)**

Use 2 mg nicotine lozenge according to the following 12 week schedule:

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

- nicotine lozenge is a medicine and must be used a certain way to get the best results
- place the lozenge in your mouth and allow the lozenge to slowly dissolve (about 20 to 30 minutes). Minimize swallowing. Do not chew or swallow lozenge.
- you may feel a warm or tingling sensation
- occasionally move the lozenge from one side of your mouth to the other until completely dissolved (about 20 to 30 minutes)
- do not eat or drink 15 minutes before using or while the lozenge is in your mouth
- to improve your chances of quitting, use at least 9 lozenges per day for the first 6 weeks
- do not use more than one lozenge at a time or continuously use one lozenge after another since this may cause you hiccups, heartburn, nausea or other side effects
- do not use more than 5 lozenges in 6 hours. Do not use more than 20 lozenges per day.
- it is important to complete treatment. If you feel you need to use the lozenge for a longer period to keep from smoking, talk to your health care provider.

**Other information**

- each lozenge contains: sodium, 18 mg
- Phenylephrine: Contains Phenylephrine 3.4 mg per lozenge
- store at 20 to 25°C (68 to 77°F)
- keep POPPAC tightly closed and protect from light

**Inactive ingredients** saccharin, aspartame, calcium polyacrylate, corn syrup solids, flavors, lactose, magnesium stearate, methylcellulose, menthol, potassium bicarbonate, sodium alginate, sodium carbonate, soy protein, triethyl citrate, xanthan gum

**Questions or comments?** call toll-free 1-888-569-7143 (English/Spanish) weekdays (9:00 am - 4:30 pm ET)

**\$5.00**  
Coupon Inside

NDC 0135-0510-06

# Nicorette

nicotine polacrifex lozenge, 2 mg  
stop smoking aid

## Lozenge

Mint

Includes User's Guide

**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 Lozenge

24 LOZENGES, 2 mg Each

**not for sale to those under 18 years of age**  
**proof of age required**  
**not for sale to vending machines or from any source where proof of age cannot be verified**

**TAMPER EVIDENT FEATURE:** Do not use if clear neckband printed "SEALED FOR SAFETY" is missing or broken.

Relief outer carton for full product uses, directions and warnings.

**TO INCREASE YOUR SUCCESS IN QUITTING:**

- You must be motivated to quit.
- Use Enough - Use at least 9 Nicorette® Lozenges per day during the first six weeks.
- Use Long Enough - Use Nicorette® Lozenges for the full 12 weeks.
- Use With a Support Program as directed in the enclosed User's Guide.

**Nicorette® POPPAC®**

To open vial, push in child resistant band on the POPPAC® container with thumb.

Flip up the top of the POPPAC® and remove lozenge. A small amount of powder on opening of the POPPAC® is normal.

For more information and for a FREE individualized stop smoking program, please visit [www.Nicorette.com](http://www.Nicorette.com) or use inside for more details.

**Drug Facts**

**Active ingredient (in each lozenge)** Nicotine polacrifex, 2 mg

**Purpose** 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 risk to your child from the medicine are not fully known.

**Do not use**

- if you are allergic to nico.

**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

**Ask a doctor or pharmacist before use if you are**

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

**Stop use and ask a doctor if**

- mouth problems occur
- persistent indigestion or severe sore throat occurs
- 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. Nicotine lozenges may have enough nicotine to make children and pets sick. If you need to remove the lozenge, wrap it 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. No studies have been done to show if this product will work for you.
- before using this product, read the enclosed User's Guide for complete directions and other important information
- begin using the lozenge on your quit day
- if you smoke your first cigarette within 30 minutes of waking up, use 4 mg nicotine lozenge
- if you smoke your first cigarette more than 30 minutes after waking up, ▶

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PS

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GSK Regulatory Spec Box		Verified Date: 5.22.15
<b>Drug Facts Info</b>		
<b>Drug Facts (Title)</b>	Font Name: Helvetica Neue 76 Bold Italic	10.00 point type
<b>Drug Facts (continued)</b>	Font Name: Helvetica Neue 76 Bold Italic/Helvetica Neue 67 Medium Condensed	8.00 point type
<b>Headings</b>	Font Name: Helvetica Neue 76 Bold Italic	8.00 point type
<b>Subheadings</b>	Font Name: Helvetica Neue 75 Bold	8.00 point type
<b>Body text</b>	Font Name: Helvetica Neue 67 Medium Condensed/Helvetica Neue 77 Bold Condensed	8.00 point type
<b>Bullets</b>	Font Name: Helvetica Neue 55 Roman	5.00 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		
Spacing of the hair lines from edge of box—Ls. Minimum of 2 spaces either side of Drug Fact Box		
Tracking	-9 to 0	Horizontal Scale: 98%-100%
Leading (Minimum space in body copy of Drug Facts)	6.40 pt.	Maximum Characters/Inch: 32
Baselines	1.00 pt.	Hairlines: 0.60 pt.
<b>Primary Display Panel Info</b>		
Font size of Net Wt/Contents (Smallest character height in inches)		0.1250 in.
PDP dimensions (in square inches)		11.86 sq. in.
Font size of Statement of Identity (if not live text, to be measured in Helvetica capital "M")		V 14.14 pt. H N/A
Font size of Logo/Largest Copy on PDP (if not live text, to be measured in Helvetica capital "M")		V 41.83 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 34% H N/A

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**Drug Facts (continued)**

4 mg nicotine lozenge according to the following 12 week schedule:

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

- nicotine lozenge is a medicine and must be used a certain way to get the best results
- place the lozenge in your mouth and allow the lozenge to slowly dissolve (about 20 to 30 minutes). Minimize swallowing. Do not chew or swallow lozenge.
- you may feel a warm or tingling sensation
- occasionally move the lozenge from one side of your mouth to the other until completely dissolved (about 20 to 30 minutes)
- do not eat or drink 15 minutes before using or while the lozenge is in your mouth
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- do not use more than one lozenge at a time or continuously use one lozenge after another since this may cause you hiccups, heartburn, nausea or other side effects
- do not use more than 5 lozenges in 6 hours. Do not use more than 20 lozenges per day.
- it is important to complete treatment. If you feel you need to use the lozenge for a longer period to keep from smoking, talk to your health care provider.

**Other information**

- each lozenge contains: sodium, 18 mg
- Phenylephrine: Contains Phenylephrine 3.4 mg per lozenge
- store at 20 to 25°C (68° - 77°F)
- keep POPPAC tightly closed and protect from light

**Inactive ingredients** saccharin, aspartame, calcium polyacrylate, corn syrup solids, flavors, lactose, magnesium stearate, methylcellulose, menthol, potassium bicarbonate, sodium alginate, sodium carbonate, soy protein, triethyl citrate, xanthan gum

**Questions or comments? call toll-free 1-888-569-1743 (English/Spanish) weekdays (8:00 am - 4:30 pm ET)**

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stop smoking aid

# Lozenge



Mint

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4  
mg

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**Drug Facts**

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Stop smoking aid

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

**Warnings**

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**Directions**

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- before using this product, read the enclosed User's Guide for complete directions and other important information
- begin using the lozenge on your quit day
- if you smoke your first cigarette more than 30 minutes after waking up, use 2 mg nicotine lozenge
- if you smoke your first cigarette within 30 minutes of waking up, use



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/s/  
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THERESA M MICHELE  
08/06/2015