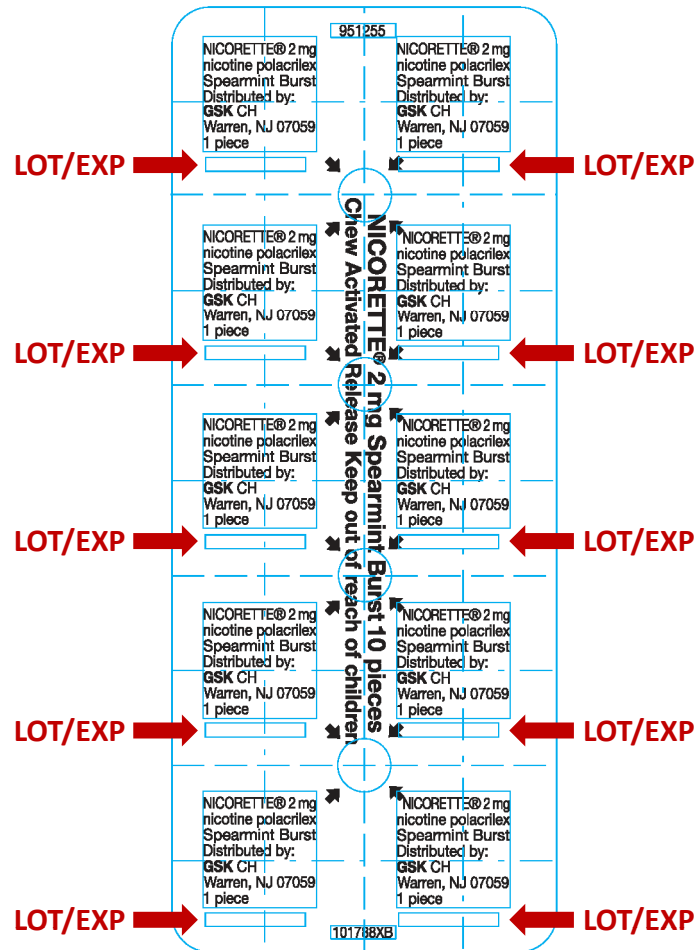


NDA 018612: Nicorette Gum, Spearmint Burst, 2 mg



GSK Regulatory Spec Box	
Verified Date: 2/20/17	
Drug Facts Info	
Drug Facts (Title)	Font Name: Helvetica Neue 76 Bold Italic
Drug Facts (continued)	Font Name: Helvetica Neue 76 Bold Italic/Helvetica Neue 57 Condensed
Headings	Font Name: Helvetica Neue 76 Bold Italic
Subheading	Font Name: Helvetica Neue 77 Bold Condensed
Body text	Font Name: Helvetica Neue 57 Condensed/ Helvetica Neue 77 Bold Condensed
Bullets	Font Name: Helvetica Neue 55 Roman
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
Leading (Minimum space in body copy of Drug Facts)	6.75 pt.
Maximum Characters/Inch:	32
Barlines	1 pt.
Horizontal Scale:	100%
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

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

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

Nicorette®
Spearmint Burst
with a hint of chamomile

PLACEMENT ANTITHEFT SURVEILLANCE TAG AREA

HERE
ANTITHEFT
PLACE
STICKER

000000

EAS Tagged

0 0000-0000-00 0

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 blisters. Do not use if individual 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

Drug Facts

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

Purpose
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 regular headache. 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
• regular headache or palpitations occur
• you get 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
• 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 tangles. Then park it between your cheek and gum. When the tangle is gone, begin chewing again, until the tangle returns.
• repeat this process until most of the tangle is gone (about 30 minutes)
• 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.

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GSK Regulatory Spec Box	
Verified Date: 01.27.17	
Drug Facts Info	
Drug Facts (Title)	Font Name: Helvetica Neue 76 Bold Italic
Drug Facts (continued)	Font Name: Helvetica Neue 76 Bold Italic/Helvetica Neue 57 Condensed
Headings	Font Name: Helvetica Neue 76 Bold Italic
Subheadings	Font Name: Helvetica Neue 77 Bold
Body text	Font Name: Helvetica Neue 77 Bold Condensed/Helvetica Neue 57 Condensed
Bullets	Font Name: Helvetica Neue 55 Roman
Bullets on same line: end of statement separated from bulleted statement by two ems	
Spacing of the hair lines from edge of box – i.e. Minimum of 2 spaces either side of Drug Fact Box	
Tracking	Horizontal Scale: 0
Leading (Minimum space in body copy of Drug Facts)	Maximum Characters/Inch: 6.75 pt.
Barlines	Hairlines 1.00 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.) H N/A V 25%	

OPEN HERE

TO INCREASE YOUR SUCCESS IN QUITTING:

- You must be motivated to quit.
- Use Enough** - Chew at least 6 pieces of Nicorette® gum per day during the first six weeks.
- Use Long Enough** - Use Nicorette® gum for the full 12 weeks.
- 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 corners with loose edge.

Push gum through foil.

160 PIECES, 4 mg EACH

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

NO VARNISH AREAS

Nicorette®

Spearmint Burst
with a hint of chamomile

EAS Tagged

0 0000-0000-00 0

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.

17-004CHFS
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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

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

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

PLACE ANTI-THEFT STICKER HERE

THEFT SURVEILLANCE TAG AREA

Lot:

Exp:

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Drug Facts

Warnings

- Use • reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking
- Nicotine polacrilex (equal to 4 mg nicotine).....Stop smoking aid

Active ingredient (in each chewing piece)

Purpose

Ask a doctor before use if you have

- sudden-onset dizziness
- heart disease, recent heart attack, or regular heartbeats. 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

- taking a non-orthodox 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
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)
- you have symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat

Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Keep 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
- 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 12 cigarettes within 30 minutes of waking up, use 4 mg nicotine gum according to the following 12 week schedule.

Weeks 1 to 6	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours
Weeks 7 to 9	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours
Weeks 10 to 12	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 tangles. Then park it between your cheek and gum. When the tangle is gone, begin chewing again, until the tangle returns.
- repeat this process until most of the tangle is gone (about 30 minutes)
- to improve your chances of quitting, use at least 9 pieces per day for the first 6 weeks
- do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece
- 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 to hiccup, 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.

NO COPY AREA

NDA 020066: Nicorette Gum, Spearmint Burst, 4 mg

