NICORETTE PEPPERMINT- nicotine polacrilex lozenge
Haleon US Holdings LLC

Drug Facts

***Active ingredient (in each lozenge)* – 2 mg**

Nicotine polacrilex, 2 mg

***Active ingredient (in each lozenge)* – 4 mg**

Nicotine polacrilex, 4 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 risks to your child from this medicine are not fully known.

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.
- 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 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,** 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. 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
- 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

- store between 20°-25°C (68°-77°F)
- keep the vial tightly closed and protect from light

Inactive ingredients

acesulfame potassium, anhydrous dibasic calcium phosphate, crospovidone, FD&C blue no. 2 aluminum lake, flavors, hypromellose, magnesium stearate, mannitol, microcrystalline cellulose, sodium bicarbonate, sodium carbonate anhydrous, sucralose, xanthan gum, xylitol

Questions or comments?

call toll-free **1-888-569-1743**

Additional Information

TO INCREASE YOUR SUCCESS IN QUITTING:

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

Opening Directions:

Squeeze child resistant tabs on each side. Flip up the top of vial. Turn upside down and shake to remove lozenge.

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

Flip open for Directions and additional information

Retain this package for complete product information

- **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**

TAMPER EVIDENT FEATURE: Do not use if clear neckband printed "SEALED FOR SAFETY" is missing or broken. Retain outer carton for full product uses, directions and warnings.

Principal Display Panel – 2 mg

NEW PEPPERMINT FLAVOR

NDC 0135-8050-20

$5.00 **Coupon Inside**

NICORETTE

nicotine polacrilex lozenge, 2 mg

stop smoking aid

mini

Lozenge

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.

20 LOZENGES, 2 mg Each

ACTUAL SIZE

PEPPERMINT

Principal Display Panel – 4 mg

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20 LOZENGES, 4 mg Each

ACTUAL SIZE

PEPPERMINT

NICORETTE PEPPERMINT

nicotine polacrilex lozenge

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-8050
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	2 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	BLUE (Blue top layer, white bottom layer)	**Score**	no score
Shape	OVAL	**Size**	11mm
Flavor	PEPPERMINT	**Imprint Code**	2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-8050-20	1 in 1 PACKAGE	09/01/2025	
1		20 in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:0135-8050-81	3 in 1 PACKAGE	09/01/2025	
2		27 in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

NDA	NDA022360	09/01/2025	

NICORETTE PEPPERMINT

nicotine polacrilex lozenge

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-8060
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	4 mg

Inactive Ingredients

Ingredient Name	Strength
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CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	BLUE (Blue top layer, white bottom layer)	**Score**	no score
Shape	OVAL	**Size**	11mm
Flavor	PEPPERMINT	**Imprint Code**	4
Contains			

Packaging

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1		20 in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:0135-8060-	3 in 1 PACKAGE	09/01/2025	

2	81	3 in 1 PACKAGE	09/01/2025	
2		27 in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022360	09/01/2025	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 7/2025 Haleon US Holdings LLC