

**NICORETTE- nicotine polacrilex lozenge**  
**Haleon US Holdings LLC**

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***Drug Facts***

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

Nicotine polacrilex, 2 mg (nicotine)

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

Nicotine polacrilex, 4 mg (nicotine)

***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**

- 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 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 (2 mg)**

- **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 (about 20 - 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 - 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.

**Directions (4 mg)**

- **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 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 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 - 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 - 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 17 mg
- Phenylketonurics: Contains Phenylalanine 5.1 mg per lozenge
- sugar alcohol content: 1 g mannitol per lozenge
- store at 20 - 25°C (68 - 77°F)
- keep vial tightly closed and protect from light

### ***Inactive ingredients***

aspartame, magnesium stearate, mannitol, natural peppermint flavor, potassium bicarbonate, sodium alginate, sodium carbonate, soy protein, xanthan gum

### ***Questions or comments?***

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

## **Additional 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 printed inner safety seal under cap is broken or missing.

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

### ***TO INCREASE YOUR SUCCESS IN QUITTING:***

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

Quit **Tube**®

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

Distributed by:

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Warren, NJ 07059

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## **Principal Display Panel**

**NDC 0135-0635-01**

**Nicorette**

nicotine polacrilex lozenge, 2 mg

stop smoking aid

**Lozenge**

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 **WITHIN30 MINUTES** of waking up, use Nicorette 4 mg Lozenge

**Mint**

**72 LOZENGES**, 2 mg Each

(3 QuitTube® Containers of 24)

NDC 0135-0635-01 

# Nicorette

nicotine polacrilex lozenge, 2 mg  
stop smoking aid

## Lozenge



Includes User's Guide

**2 mg**

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**Principal Display Panel**

**NDC 0135-0636-01**

**Nicorette**

nicotine polacrilex lozenge, 4 mg

stop smoking aid

## **Lozenge**

Includes User's Guide

**4 mg**

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

**Mint**

**72 LOZENGES**, 4 mg Each

(3 QuitTube<sup>®</sup> Containers of 24)

84LB9SBC1-NRO - Front Carton

NDC 0135-0636-01

gsk

# Nicorette

nicotine polacrilex lozenge, 4 mg  
stop smoking aid

## Lozenge



Includes User's Guide

**4**  
**mg**

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SMOKE THEIR FIRST  
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*Mint*

72 LOZENGES, 4 mg Each  
(3 QuitTube®  
Containers of 24)

### NICORETTE

nicotine polacrilex lozenge

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0635
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)		NICOTINE	2 mg	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
POLACRILIN (UNII: RCZ785HI7S)				
ASPARTAME (UNII: Z0H242BBR1)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MANNITOL (UNII: 3OWL53L36A)				
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)				
SODIUM ALGINATE (UNII: C269C4G2ZQ)				
SODIUM CARBONATE (UNII: 45P3261C7T)				
XANTHAN GUM (UNII: TTV12P4NEE)				
<b>Product Characteristics</b>				
Color	white (white to off-white)	Score	no score	
Shape	ROUND	Size	16mm	
Flavor	MINT	Imprint Code	L344	
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0635-01	3 in 1 CARTON	06/01/2022	
1		72 in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:0135-0635-02	6 in 1 CARTON	06/01/2022	
2		144 in 1 CONTAINER; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA021330	06/01/2022		

NICORETTE			
nicotine polacrilex lozenge			
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Ingredient Name	Basis of Strength	Strength
<b>NICOTINE</b> (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	4 mg

**Inactive Ingredients**

Ingredient Name	Strength
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<b>ASPARTAME</b> (UNII: Z0H242BBR1)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>POTASSIUM BICARBONATE</b> (UNII: HM5Z15LEBN)	
<b>SODIUM ALGINATE</b> (UNII: C269C4G2ZQ)	
<b>SODIUM CARBONATE</b> (UNII: 45P3261C7T)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

**Product Characteristics**

<b>Color</b>	white (white to off-white)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	16mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	L873
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0636-01	3 in 1 CARTON	06/01/2022	
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2	NDC:0135-0636-02	6 in 1 CARTON	06/01/2022	
2		144 in 1 CONTAINER; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021330	06/01/2022	

**Labeler** - Haleon US Holdings LLC (079944263)