

**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

***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 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. 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.

**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. 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 at 20 - 25°C (68 - 77°F)
- store in the original container

#### ***Inactive ingredients***

acesulfame potassium, flavors, hypromellose, magnesium stearate, mannitol, microcrystalline cellulose, polysorbate 80, potassium aluminum silicate, sodium carbonate anhydrous, sucralose, titanium dioxide, 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:**The lozenge container is protected in a clear plastic shell, sealed to a printed card.

Do not use if the printed card or plastic shell is torn or broken, or if there is any evidence that the printed card was separated from the plastic shell.

**Retain this package for complete product information.**

Includes Quit Support Program

**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 for the full 12 weeks.**
4. **Use With a Support Program as directed in the enclosed User's Guide.**

**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.**

**TO OPEN**

**PUSH**

**LIFT**

**TO CLOSE**

**Push Cap Closed until you hear a CLICK to ensure child resistance**

**CLICK**

Distributed By:

**Haleon**

Warren, NJ 07059

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**Principal Display Panel**

**NDC 0135-0625-01**

**HALEON**

**NICORETTE**

**nicotine polacrilex lozenge, 2 mg | stop smoking aid**

**Lozenge**

**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.

**SUGAR FREE**

**20 LOZENGES, 2 mg EACH(1 Pack of 20)**

Includes User's Guide

**Coated Ice Mint**

216965

NDC 0135-0625-01

HALEON

# NICORETTE

nicotine polacrilex lozenge, 2 mg | stop smoking aid  
Lozenge

**2 mg**

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SMOKE THEIR  
FIRST CIGARETTE  
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AFTER WAKING UP.

If you smoke your  
first cigarette  
**WITHIN 30 MINUTES**  
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Nicorette 4 mg  
Lozenge.

**SUGAR  
FREE**

20 LOZENGES  
2 mg EACH (1 Pack of 20)



ACTUAL  
SIZE

Includes  
User's Guide

**Coated  
Ice Mint**

**Principal Display Panel**

**NDC 0135-0626-01**

**HALEON**

**NICORETTE**

**nicotine polacrilex lozenge, 4 mg | stop smoking aid**

## Lozenge

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 Lozenge.

**SUGAR FREE**

**20 LOZENGES, 4 mg EACH(1 Pack of 20)**

Includes User's Guide

**Coated Ice Mint**

216969

NDC 0135-0625-01 HALEON

# NICORETTE

nicotine polacrilex lozenge, 4 mg | stop smoking aid  
Lozenge

**4mg**

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 Lozenge.

**SUGAR FREE**

20 LOZENGES  
4 mg EACH (1 Pack of 20)

Includes User's Guide

**Coated Ice Mint**

ACTUAL SIZE

# NICORETTE

nicotine polacrilex lozenge

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0625
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>NICOTINE</b> (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	2 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>POLACRILIN</b> (UNII: RCZ785HI7S)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POTASSIUM</b> (UNII: RWP5GA015D)	
<b>ALUMINUM SILICATE</b> (UNII: T1FAD4SS2M)	
<b>SODIUM CARBONATE</b> (UNII: 45P3261C7T)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	white (white to off-white)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	15mm
<b>Flavor</b>	MINT (Ice Mint)	<b>Imprint Code</b>	n;2
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0135-0625-01	1 in 1 CARTON	04/11/2019	
1		20 in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:0135-0625-02	4 in 1 CARTON	04/11/2019	
3		20 in 1 CONTAINER; Type 0: Not a Combination		

4		Product	
3	NDC:0135-0625-03	6 in 1 CARTON	10/23/2019
3		20 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	04/11/2019	

## NICORETTE

nicotine polacrilex lozenge

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0626
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>POLACRILIN</b> (UNII: RCZ785HI7S)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POTASSIUM</b> (UNII: RWP5GA015D)	
<b>ALUMINUM SILICATE</b> (UNII: T1FAD4SS2M)	
<b>SODIUM CARBONATE</b> (UNII: 45P3261C7T)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	white (white to off-white)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	15mm
<b>Flavor</b>	MINT (Ice Mint)	<b>Imprint Code</b>	n;4
<b>Contains</b>			

**Packaging**

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1		20 in 1 CONTAINER; Type 0: Not a Combination Product		
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2		20 in 1 CONTAINER; Type 0: Not a Combination Product		
3	NDC:0135-0626-03	6 in 1 CARTON	10/23/2019	
3		20 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	04/11/2019	

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

Revised: 6/2025

Haleon US Holdings LLC