

**NICOTINE MINI- nicotine polacrilex lozenge**  
**Rugby Laboratories, Inc.**

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**Drug Facts**

**Active ingredient (in each lozenge)**

Nicotine polacrilex 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 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 (1-800-222-1222).

### Directions (2 mg lozenge)

- **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

- Phenylketonurics: Contains Phenylalanine 2.8 mg per lozenge
- store at 20-25°C (68-77°F)
- keep bottle tightly closed and protect from light

### Inactive ingredients

aspartame, calcium polycarbophil, flavor, maltodextrin, mannitol, sodium alginate, sodium bicarbonate, sodium stearyl fumarate, talc, xanthan gum

### **Questions or comments?**

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

### **Principal Display Panel (2 mg lozenge)**

compare to the active ingredient in Nicorette® *mini* Lozenge\*

#### **nicotine**

#### **mini Lozenge**

Nicotine polacrilex 2 mg

Stop Smoking Aid

Mint Flavor

#### **2 mg**

User's Guide Included

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 Nicotine Polacrilex 4 mg Lozenge

**LOZENGES**, 2 mg Each (Vials)

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

1. You must be motivated to quit.
2. **Use Enough** - Use **at least 9** Nicotine mini lozenges per day during the first six weeks.
3. **Use Long Enough** - Use Nicotine mini lozenges for the full 12 weeks.
4. **Use With a Support Program** as directed in the enclosed User's Guide.
  - **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 not manufactured or distributed by Haleon group of companies, distributor of Nicorette® *mini* Lozenge.

**See inside for more detail or visit [www.nixthehabit.com](http://www.nixthehabit.com)**

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

**RETAIN OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

Distributed by:

**RUGBY® LABORATORIES**

**Indianapolis, IN 46268**

**Package Label (2 mg lozenge)**

<b>Drug Facts</b>		
<b>Active ingredient (in each lozenge)</b> Nicotine polacrilex 2 mg	<b>Purpose</b> Stop smoking aid	
<b>Use</b> reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking		
<b>Warnings</b> 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.		
<b>Ask a doctor before use if you have</b> 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		
<b>Ask a doctor or pharmacist before use if you are</b> using a non-nicotine stop smoking drug taking prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.		
<b>Stop use and ask a doctor if</b> 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)		
<b>Keep out of reach of children and pets.</b> 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 (1-800-222-1222).		
<b>Directions</b> 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
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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		

**Drug Facts (continued)**

- 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.
- 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**

- Pharmaceutical: Contains Phenylalanine 2.8 mg per lozenge
- Store at 20°-25°C (68°-77°F)
- Keep bottle tightly closed and protect from light.

**Inactive ingredients:** aspartame, calcium polycarboxylate, flavor, malto-dextrin, mannitol, sodium alginate, sodium bicarbonate, sodium stearoyl fumarate, talc, xanthan gum

**Questions or comments?**  
Call 1-877-753-8805 Monday-Friday 9AM-5PM EST

This product is not manufactured or distributed by Halseon group of companies, distributor of Nicorette® mini Lozenge.

**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**



NDC 0536-1239-81

compare to the active ingredient in Nicorette® mini Lozenge®

# nicotine mini lozenge

**nicotine polacrilex 2 mg stop smoking aid**

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 Nicotine Polacrilex 4 mg Lozenge

**2 mg** User's Guide included

**81 lozenges, 2 mg each** (3 bottles of 27)

mint flavor



actual size

Distributed by:  
**RUGBY® LABORATORIES**  
Indianapolis, IN 46268  
(800) 616-2471  
www.major-rugby.com

PLD-B216E F0209122  
Rev. 12/24 R-56 Re-order No. 370785



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**TAMPER EVIDENT. DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

**RETAIN OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

Lot No:  
Exp. Date:

- Opening Directions:**  
Push down on cap and turn to open.
- TO INCREASE YOUR SUCCESS IN QUITTING:**
- You must be motivated to quit.
  - Use Enough** - Use at least 9 nicotine mini lozenges per day during the first six weeks.
  - Use Long Enough** - Use nicotine mini lozenges for the full 12 weeks.
  - Use With a Support Program** as directed in the enclosed User's Guide.

**RUGBY Nicotine Mini Lozenge Mint Flavor**

<b>NICOTINE MINI</b>			
nicotine polacrilex lozenge			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-1239
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)		NICOTINE	2 mg
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>

<b>ASPARTAME</b> (UNII: Z0H242BBR1)	
<b>CALCIUM POLYCARBOPHIL</b> (UNII: 8F049NKY49)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>SODIUM ALGINATE</b> (UNII: C269C4G2ZQ)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	129
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1239-81	3 in 1 BOX	07/31/2019	
1		27 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0536-1239-27	1 in 1 BOX	07/31/2019	
2		27 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207868	07/31/2019	

**Labeler** - Rugby Laboratories, Inc. (079246066)