

NICOTINE- nicotine polacrilex lozenge
Rugby Laboratories, Inc.

Drug Facts

Active ingredient (in each lozenge)

Nicotine polacrilex USP, 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

- 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 (1-800-222-1222) 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 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 to 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 to 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 14 mg
- store at 20° to 25°C (68° to 77°F)
- keep bottle tightly closed and protect from light

Inactive ingredients

acesulfame potassium, colloidal silicon dioxide, flavor, hydroxypropyl cellulose, magnesium stearate, mannitol, potassium bicarbonate, povidone, sodium alginate, sodium carbonate, sucralose, xanthan gum

Questions or comments?

Call **1-800-645-2158**

Principal Display Panel

Compare to the active ingredient in Nicorette® Lozenge*

Nicotine Polacrilex Lozenges

Stop Smoking Aid

2 mg

Mint Flavor

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP.

If you smoke your first cigarette **WITHIN 30 MINUTES** after waking up, use 4 mg Nicotine Polacrilex Lozenge.

LOZENGES

TO INCREASE YOUR SUCCESS IN QUITTING:

- 1.** You must be motivated to quit.
- 2. Use Enough** - Use **at least 9 Nicotine Polacrilex** lozenges per day during the first six weeks.
- 3. Use Long Enough** - Use **Nicotine Polacrilex** 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 GlaxoSmithKline Consumer Healthcare, L.P., distributor of Nicorette® Lozenge.

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

KEEP OUTER CARTON FOR FULL PRODUCT USES, DIRECTIONS AND WARNINGS.

Distributed by:

RUGBY® LABORATORIES

Livonia, MI 48152

www.rugbylaboratories.com

Package Label

Drug Facts

Active ingredient (in each lozenge) Nicotine polacrilex USP 2 mg. **Purpose** Stop smoking aid

Use
 ■ reduce withdrawal symptoms, including relative 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 (1-800-222-1222) 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 5 | Weeks 6 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 30 to 30 minutes). 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 (about 30 to 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 dizziness, headache, nausea or other side effects
 ■ Do not use more than 9 lozenges in 8 hours. Do not use more than 36 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 14 mg
 ■ Store at 20° to 25°C (68° to 77°)
 ■ Keep bottle tightly closed and protect from light

Inactive ingredients: acacia/kumari potassium, colloidal silicon dioxide, flavors, hydroxypropyl cellulose, magnesium stearate, mannitol, potassium bicarbonate, povidone, sodium alginate, sodium carbonate, sucralose, xanthan gum

Questions or comments?
 Call 1-800-646-2158

*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, L.P., distributor of Nicorette® Lozenges.

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

RETAIN OUTER CARTON FOR FULL PRODUCT USES, DIRECTIONS AND WARNINGS.

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 0536-1337-09
Compare to the active ingredient in Nicorette® Lozenge®

Nicotine Polacrilex Lozenge

Stop Smoking Aid

2 mg

Mint Flavor

Actual Size

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 4 mg Nicotine Polacrilex Lozenge

72 Lozenges, 2 mg EACH

3 Containers of 24

Rev. 07/21 R-58 Re-order No. 371016
3 05361 33709 4

PLD A638A F0007854

Lot No:
Exp. Date:

TO INCREASE YOUR SUCCESS IN QUITTING:

- You must be motivated to quit.
- Use Enough** - Use at least 9 Nicotine Polacrilex Lozenges per day during the first six weeks.
- Use Long Enough** - Use Nicotine Polacrilex Lozenges for the full 12 weeks.
- Use With a Support Program** as directed in the enclosed User's Guide.

RUGBY Nicotine Polacrilex Lozenge Mint Flavor

NICOTINE

nicotine polacrilex lozenge

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0536-1337 |
| 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) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MANNITOL (UNII: 3OWL53L36A) | |
| POTASSIUM BICARBONATE (UNII: HM5Z15LEBN) | |
| POVIDONE (UNII: FZ989GH94E) | |
| SODIUM ALGINATE (UNII: C269C4G2ZQ) | |
| SODIUM CARBONATE (UNII: 45P3261C7T) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | white | Score | no score |
| Shape | ROUND | Size | 16mm |
| Flavor | MINT | Imprint Code | A627 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0536-1337-09 | 3 in 1 BOX | 09/17/2021 | |
| 1 | | 24 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 | ANDA209206 | 09/17/2021 | |

Labeler - Rugby Laboratories, Inc. (079246066)

Revised: 12/2022

Rugby Laboratories, Inc.