

NICOTINE MINI- nicotine polacrilex lozenge
Rising Pharma Holdings, Inc.

Drug Facts

Active ingredient (in each lozenge)

Nicotine polacrilex 4 mg

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 (4 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 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.

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 **1-844-474-7464**

Distributed by:

Rising Pharma Holdings, Inc.

East Brunswick, NJ 08816

Issued: 04/2023

Principal Display Panel (4 mg lozenge)

*Compare to the active ingredient in Nicorette® *mini* Lozenge

Nicotine Mini Lozenge

Stop Smoking Aid

NICOTINE POLACRILEX LOZENGE 4 MG

- **User's Guide Included**
- **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 Nicotine Polacrilex 2 mg Lozenge.**

4 mg

NDC 57237-321-42 (1 Bottle of 24)

Mint Flavor

LOZENGES, 4 mg Each (Bottles)

Opening Directions:

Push down on cap and turn to open.

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 GlaxoSmithKline Consumer Healthcare, L.P., distributor of Nicorette® mini Lozenge

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

RETAIN OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Package Label (4 mg lozenge)

NO PRINT
NO VARNISH
NO COATING

The product is not meant to be used or distributed by
the holder of Nicorette® mini Lozenges.

Issued: 04/2023
Distributed by:
Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Drug Facts (continued)
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. 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.

Drug Facts (continued)

- 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

- Phenylethanolamine: Contains Phenylethanolamine 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 1-844-474-7464

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

Opening Directions:
Push down on cap and turn to open.

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.

Rising HEALTH NDC 57237-321-42
 *Compare to the active ingredient in Nicorette® mini Lozenge

Nicotine Mini Lozenge

Stop Smoking Aid

NICOTINE POLACRILEX LOZENGE 4 MG

- User's Guide Included
- 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 Nicotine Polacrilex 2 mg Lozenge.

4 mg

24 Lozenges, 4 mg each (1 Bottle of 24)

Mint Flavor Actual Size

Drug Facts
Active ingredient (in each lozenge) Purpose
 Nicotine polacrilex 4 mg 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.

100495Q1
PRINT SIDE GLUE

NO PRINT
NO VARNISH
NO COATING

PLD-A215E F000627



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:

Need at least 30 lbs. for Lot/Box to print



NDC 57237-321-42

4
mg

Nicotine Mini Lozenge

Stop Smoking Aid

NICOTINE POLACRILEX LOZENGE 4 MG

24 Lozenges



Mint Flavor

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Retain outer carton for full product uses, directions and warnings. Keep bottle tightly closed and protect from light. Discard bottle after use. Tamper Evident Feature: Do not use if printed safety seal under cap is broken or missing.

Store at 20-25°C (68-77°F).

Questions or comments? Call 1-844-474-7464

Issued: 04/2023

Distributed by:

Rising Pharma Holdings, Inc.

East Brunswick, NJ 08816

PLD-A215E

LB009306

Lot No.:

Exp. Date:

Principal Display Panel (2 mg lozenge)

*Compare to the active ingredient in Nicorette[®] mini Lozenge

Nicotine Mini Lozenge

Stop Smoking Aid

NICOTINE POLACRILEX LOZENGE 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.**

2 mg

NDC 57237-320-42 (1 Bottle of 24)

Mint Flavor

LOZENGES, 2 mg Each (Bottles)

Opening Directions:

Push down on cap and turn to open.

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 GlaxoSmithKline Consumer Healthcare, L.P., distributor of Nicorette® mini Lozenge

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

RETAIN OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Package Label (2 mg lozenge)

NO PRINT
NO VARNISH
NO COATING

*This product is not an antidepressant or antidepressant
distributor of Nicorette® mini lozenges.

Issued: 04/2023
Distributed by:
Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

100495Q1
PRINT SIDE GLUE

Drug Facts (continued)

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 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.

Drug Facts (continued)

■ 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

- Phenylethanols: Contains Phenylethanol 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, maltodextrin, mannitol, sodium alginate, sodium bicarbonate, sodium stearyl fumarate, talc, xanthan gum

Questions or comments? Call 1-844-474-7464

- 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

Opening Directions:

Push down on cap and turn to open.

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.



NDC 57237-320-42

*Compare to the active ingredient in Nicorette® mini Lozenge

Nicotine Mini Lozenge

Stop Smoking Aid

NICOTINE POLACRILEX LOZENGE 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.**

2 mg

24 Lozenges, 2 mg each
(1 Bottle of 24) Mint Flavor Actual Size



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:

Place at least 30 in. for
Lift-Up to print

Drug Facts

Active ingredient (in each lozenge) Purpose
Nicotine polacrilex 2 mg.....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.



NDC 57237-320-42

2
mg**Nicotine Mini Lozenge****Stop Smoking Aid**

NICOTINE POLACRILEX LOZENGE 2 MG

24 Lozenges

Mint Flavor

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Retain outer carton for full product uses, directions and warnings. Keep bottle tightly closed and protect from light. Discard bottle after use. Tamper Evident Feature: Do not use if printed safety seal under cap is broken or missing.

Store at 20-25°C (68-77°F).

Questions or comments? Call 1-844-474-7464

Issued: 04/2023

Distributed by:Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816PLD-A216E
LB009307

Lot No.:

Exp. Date:

NICOTINE MINI

nicotine polacrilex lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-321
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
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM POLYCARBOPHIL (UNII: 8F049NKY49)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MANNITOL (UNII: 3OWL53L36A)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TALC (UNII: 7SEV7J4R1U)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	10mm
Flavor	MINT	Imprint Code	131
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-321-42	1 in 1 BOX	08/10/2023	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:57237-321-72	3 in 1 BOX	08/10/2023	
2		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	ANDA207868	08/10/2023	

NICOTINE MINI

nicotine polacrilex lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-320
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)		NICOTINE	2 mg	
Inactive Ingredients				
Ingredient Name			Strength	
ASPARTAME (UNII: Z0H242BBR1)				
CALCIUM POLYCARBOPHIL (UNII: 8F049NKY49)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
MANNITOL (UNII: 3OWL53L36A)				
SODIUM ALGINATE (UNII: C269C4G2ZQ)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)				
TALC (UNII: 7SEV7J4R1U)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Product Characteristics				
Color	white	Score	no score	
Shape	OVAL	Size	10mm	
Flavor	MINT	Imprint Code	129	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-320-42	1 in 1 BOX	08/10/2023	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:57237-320-72	3 in 1 BOX	08/10/2023	
2		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	ANDA207868	08/10/2023		

Labeler - Rising Pharma Holdings, Inc. (116880195)