

NICOTINE MINI- nicotine polacrilex lozenge
PLD Acquisitions LLC DBA Avéma Pharma Solutions

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.

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 vial 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 (4 mg lozenge)

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

Mini

Nicotine Lozenge

Nicotine Polacrilex Lozenge

4 mg

Stop Smoking Aid

Mint Flavor

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

LOZENGES, 4 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 GlaxoSmithKline Consumer Healthcare, L.P., distributor of Nicorette® *mini* Lozenge.

Manufactured by:

Avéma Pharma Solutions

10400 NW 29th Terrace

Miami, FL 33172

RETAIN OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

For more information and for a free individual stop smoking program, please call (1-877-753-3935) or see inside for more details.

Package Label (4 mg lozenge)



Drug Facts

Active ingredient (in each lozenge)
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 (1-800-222-1222).

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:

Drug Facts (continued)

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

- use 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 6 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 Phenylethylamine 2.8 mg per lozenge
- store at 20°-25° (68°-77°)
- keep vial tightly closed and protect from light.

Inactive ingredients: aspartame, calcium polycarboxyl, 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

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

*Compare to the active ingredient in Nicorette® mini Lozenge
NDC 63548-0264-0



Nicotine Lozenge

Nicotine Polacrilex Lozenge
4 mg
Stop Smoking Aid

Mint Flavor

4 mg

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

108 LOZENGES,
4 mg Each
(4 Vials of 27)

Users Guide Included

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.

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

RETAIN OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

For more information and for a free individualized stop smoking program, please call (1-877-753-3935) or see inside for more details.

Manufactured by:
Ardina Pharma Solutions
10400 NW 29th Terrace
Miami, FL 33172



Lot No.:
Exp. Date:

Nicotine polacrilex lozenge mini 4 mg

Principal Display Panel (2 mg lozenge)

Compare to the active ingredient in Nicorette® mini Lozenge*

Mini

Nicotine Lozenge

Nicotine Polacrilex Lozenge

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.
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Manufactured by:

Avéma Pharma Solutions

10400 NW 29th Terrace

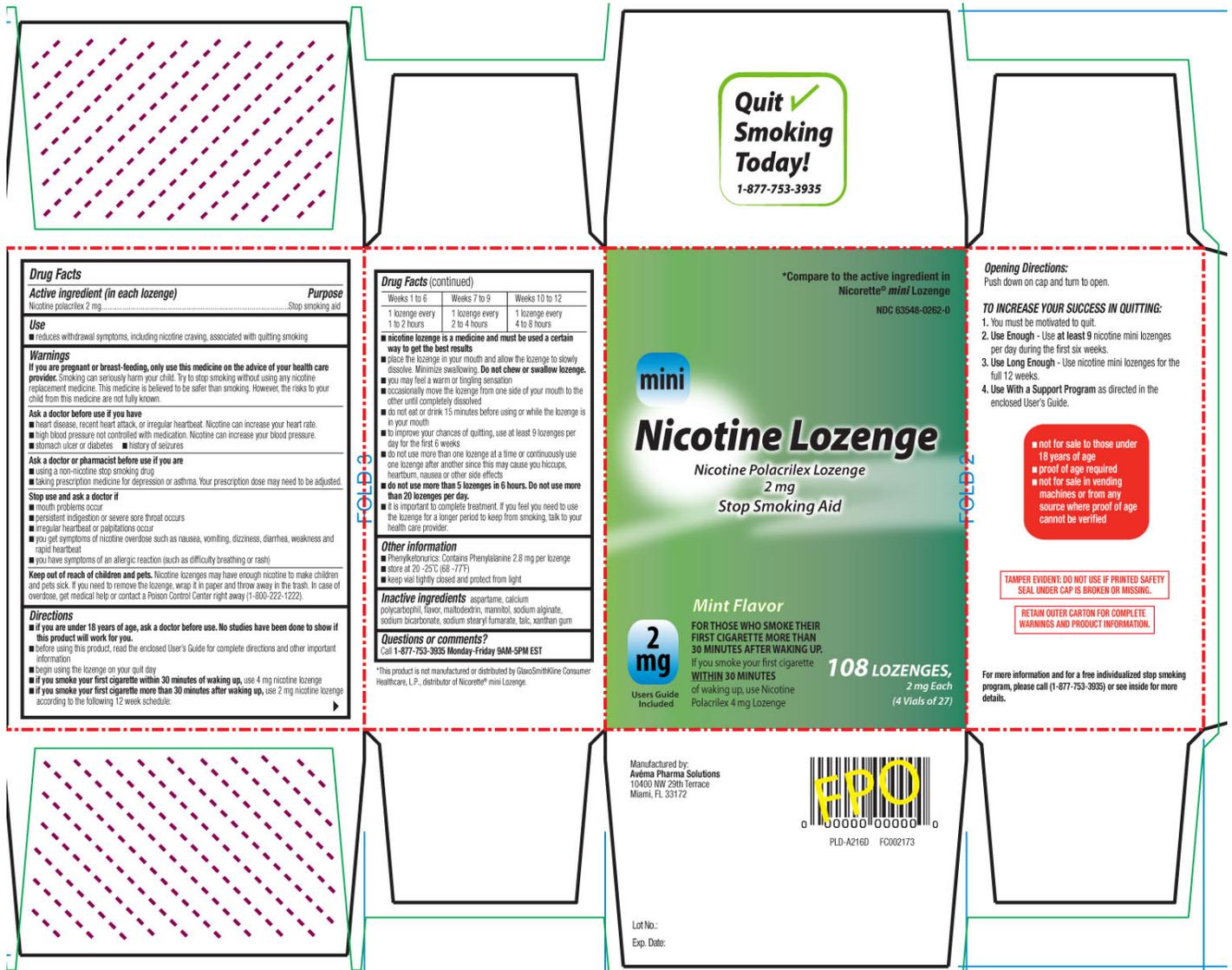
Miami, FL 33172

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

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Package Label (2 mg lozenge)



Nicotine polacrilex lozenge mini 2mg

NICOTINE MINI

nicotine polacrilex lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63548-0264
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:63548-0264-7	1 in 1 BOX	04/01/2019	
1		27 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:63548-0264-1	3 in 1 BOX	04/01/2019	
2		27 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:63548-0264-0	4 in 1 BOX	04/01/2019	
3		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	04/01/2019	

NICOTINE MINI

nicotine polacrilex lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63548-0262
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
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:63548-0262-7	1 in 1 BOX	04/01/2019	
1		27 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:63548-0262-1	3 in 1 BOX	04/01/2019	
2		27 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:63548-0262-0	4 in 1 BOX	04/01/2019	
3		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	04/01/2019	

Labeler - PLD Acquisitions LLC DBA Avéma Pharma Solutions (804087794)