

NICOTINE MINI- nicotine polacrilex lozenge
Advagen Pharma Limited

Drugs 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

- Each lozenge contains: sodium, 5 mg
- store at 20 ° to 25 °C (68 ° to 77 °F)
- keep bottle tightly closed and protect from light
- 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.

Inactive ingredients

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

Questions or comments?

Call **866-488-0312** Monday-Friday 9AM-5PM EST

Manufactured by

Rubicon Research Pvt. Ltd
Ambarnath, Maharashtra 421 506, India

Manufactured for

Advagen Pharma Limited,
666 Plainsboro Road, Suite 605
Plainsboro, NJ 08536, USA

Revised - April 2023

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Nicotine Polacrilex Lozenge, 2 mg - NDC 72888-186-53 - 27s Container Label

NDC 72888-186-53

Nicotine Polacrilex Lozenge, 2 mg

STOP SMOKING AID



Mint

mini Lozenge

27 Lozenges, 2 mg Each

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 seal under cap is broken or missing.

Store at 20° to 25°C (68° to 77°F).

Questions? 866-488-0312 between 9 am and 5 pm ET, Monday-Friday.

Manufactured by: Rubicon Research Pvt. Ltd, Ambarnath, Maharashtra 421 506, India

Distributed by: Advagen Pharma Limited, 666 Plainsboro Road Suite 605, Plainsboro, NJ, 08536, USA

Rev. 04/23



Lot:

Exp.:

Nicotine Polacrilex Lozenge, 2 mg - NDC 72888-186-53 - 27s Carton Label

Drug Facts (continued)

- 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

- each lozenge contains sodium, 5 mg
- store at 20° to 25°C (68° to 77°)
- keep bottle tightly closed and protect from light
- 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.

Inactive ingredients

saccharine potassium, colloidal silicon dioxide, flavors, hydroxypropyl methylcellulose, magnesium stearate, xanthan gum, potassium bicarbonate, polydioxane, sodium alginate, sodium carbonate, sucralose, and xanthan gum.

Questions? Call 800-488-0312 Monday-Friday 9AM-5PM EST

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Manufactured by: Rubicon Research Pvt. Ltd
Ambemath, Maharashtra 421 506, India

Distributed by: Advagen Pharma Limited,
806 Plainsboro Road Suite 805,
Plainsboro, NJ 08538, USA

Rev: 04/23

NDC 72888-186-53
*Compare to the active ingredient in Nicorette® Lozenge

Nicotine Polacrilex Lozenge, 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 the 4 mg Nicotine Polacrilex Lozenge.

mini Lozenge

27 Lozenges, 2 mg Each



Mint
ADVAGEN

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. Use 4mg - Use at least 9 Nicotine Polacrilex Lozenges per day during the first 6 weeks.
3. Use 2mg Lozenge - Use Nicotine Polacrilex Lozenges for the full 12 weeks.
4. Use WITH a support program as detailed 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.



Lot:
Exp.:

Drug Facts

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

Use

- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

- If you are pregnant or breastfeeding, 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 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.

Nicotine Polacrilex Lozenge, 2 mg - NDC 72888-186-54 - 81s Carton Label

Drug Facts (continued)

- 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

- each lozenge contains: sodium, 5 mg
- store at 20° to 25°C (68° to 77°F)
- keep bottle tightly closed and protect from light
- TAMPER EVIDENT FEATURES: Do not use if printed seal under cap is broken or missing
- retain outer carton for full product uses, directions and warnings

Inactive ingredients

zinc sulfate, potassium, colloidal silicon dioxide, flavors, hydroxypropyl cellulose, magnesium stearate, mannitol, potassium bicarbonate, polydioxane, sodium alginate, sodium carbonate, sucralose, and xanthan gum.

Questions? Call 800-488-0312 Monday-Friday 9AM-5PM EST

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Manufactured by: Rubicon Research Pvt. Ltd
Ambemath, Maharashtra 421 506, India

Distributed by: Advagen Pharma Limited,
606 Plainboro Road Suite 605,
Plainboro, NJ, 08538, USA
Rev. 04/23

NDC 72888-186-54
*Compare to the active ingredient in Nicorette® Lozenge

Nicotine Polacrilex Lozenge, 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 the 4 mg Nicotine Polacrilex Lozenge.

mini Lozenge

81 Lozenges, 2 mg Each
(3 bottles of 27)



TO INCREASE YOUR SUCCESS IN QUITTING:

1. Use **one** lozenge per day during the first 6 weeks.
2. Use **two** lozenges per day during the full 12 weeks.
3. Use **four** lozenges per day during the full 12 weeks.
4. Use with a support program as defined 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.



Lot:
Exp.:

Drug Facts

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

Use

- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

- If you are pregnant or breastfeeding, 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 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.

Nicotine Polacrilex Lozenge, 2 mg - NDC 72888-186-55 - 108s Carton Label

Drug Facts (continued)

- 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 eye irritation, 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, 5 mg
- store at 20° to 25°C (68° to 77°)
- keep bottle tightly closed and protect from light
- 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

Inactive ingredients
saccharine potassium, colloidal silicon dioxide, flavor, hydroxypropyl cellulose, magnesium stearate, croscarmellose potassium, croscarmellose potassium, sodium alginate, sodium carboxymethyl cellulose, xanthan gum.

Questions? Call 866-488-0312 Monday-Friday 9AM-5PM EST

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Manufactured by: Rubicon Research Pvt. Ltd
Ambemath, Maharashtra 421 506, India

Distributed by: Advagen Pharma Limited,
606 Plainsboro Road Suite 605,
Plainsboro, NJ 08538, USA

Rev. 04/23

NDC 72888-186-55
*Compare to the active ingredient in Nicorette® Lozenge

Nicotine Polacrilex Lozenge, 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 the 4 mg Nicotine Polacrilex Lozenge.

mini Lozenge

108 Lozenges, 2 mg Each
(4 bottles of 27)



Mint
ADVAGEN

TO INCREASE YOUR SUCCESS IN QUITTING:

1. Use **one** 2 mg Nicotine Polacrilex Lozenge per day during the first 6 weeks.
2. Use **two** 4 mg Nicotine Polacrilex Lozenges for the full 12 weeks.
3. Use **one** 2 mg Nicotine Polacrilex Lozenge for the full 12 weeks.
4. Use **with** a support program as defined 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.



Lot:
Exp.:

Drug Facts

Active ingredient (in each lozenge) Nicotine polacrilex USP, 2 mg	Purpose Stop smoking aid
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Use
• reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

- If you are pregnant or breastfeeding, 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 (rash or difficulty breathing or rash)

Keep out of reach of children and pets. Nicotine lozenge 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 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.

Nicotine Polacrilex Lozenge, 2 mg - NDC 72888-186-56 - 135s Carton Label

Drug Facts (continued)

- 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 8 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, 5 mg
- store at 20° to 25°C (68° to 77°)
- keep bottle tightly closed and protect from light
- **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.

Inactive ingredients

aerosolized potassium, colloidal silicon dioxide, flavors, hydroxypropyl cellulose, magnesium stearate, mannitol, potassium bicarbonate, povidone, sodium alginate, sodium carbonate, saccharin, and xanthan gum.

Questions? Call 866-488-0312 Monday-Friday 9AM-5PM EST

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Ambemath, Maharashtra 421 506, India

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606 Plainsboro Road Suite 605,
Plainsboro, NJ, 08538, USA

Rev. 04/23

NDC 72888-186-56
*Compare to the active ingredient in Nicorette® Lozenge

Nicotine Polacrilex Lozenge, 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 the 4 mg Nicotine Polacrilex Lozenge.

mini Lozenge

135 Lozenges, 2 mg Each
(5 bottles of 27)



Mint
ADVAGEN

TO INCREASE YOUR SUCCESS IN QUITTING:

1. Use each lozenge as directed.
2. Use Strength 1 for the first 12 weeks.
3. Use Strength 2 for the last 12 weeks.
4. Use with a support program as defined 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.



Lot:
Exp.:

Drug Facts

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

Use

- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

- If you are pregnant or breastfeeding, 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 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.

Nicotine Polacrilex Lozenge, 4 mg - NDC 72888-187-53 - 27s Container Label

NDC 72888-187-53

Nicotine Polacrilex Lozenge, 4 mg

STOP SMOKING AID

mini Lozenge



Mint

27 Lozenges, 4 mg Each

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 seal under cap is broken or missing.

Store at 20° to 25°C (68° to 77°F).

Questions? 866-488-0312 between 9 am and 5 pm ET, Monday-Friday.

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Distributed by: Distributed by: Advagen Pharma Limited, 666 Plainsboro Road Suite 605, Plainsboro, NJ, 08536, USA

Rev. 04/23



Lot:

Exp.:

Nicotine Polacrilex Lozenge, 4 mg - NDC 72888-187-53 - 27s Carton Label

Drug Facts (continued)

- 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 8 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, 5 mg
- store at 20° to 25°C (68° to 77°F)
- keep bottle tightly closed and protect from light
- 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.

Inactive ingredients

saccharin potassium, colloidal silicon dioxide, flavors, hydroxypropyl cellulose, magnesium stearate, croscarmellose potassium, polyvinylpyrrolidone, sodium alginate, sodium carbonate, sucralose, and xanthan gum.

Questions? Call 800-488-0312 Monday-Friday 9AM-5PM EST

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Ambemath, Maharashtra 421 506, India

Distributed by: AdvaGen Pharma Limited,
606 Plattsboro Road Suite 010,
Plattsboro, NJ 08538, USA

Rev. 04/23

NDC 72888-187-53
*Compare to the active ingredient in Nicorette® Lozenge

Nicotine Polacrilex Lozenge, 4 mg

STOP SMOKING AID

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 the 2 mg Nicotine Polacrilex Lozenge.

mini Lozenge
27 Lozenges, 4 mg Each



TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. Use Lozenge - Use at least 9 Nicotine Polacrilex Lozenges per day during the first 6 weeks.
3. Use Long Strength - Use Nicotine Polacrilex Lozenges for the full 12 weeks.
4. Use with a support program as detailed 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.



Lot:
Exp.:

Drug Facts

Active ingredient (in each lozenge)	Purpose
Nicotine polacrilex, USP, 4 mg	Stop smoking aid

Use

- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

- If you are pregnant or breastfeeding, 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 lozenge 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:

Weeks 1 to 6	Weeks 7 to 8	Weeks 9 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.

Nicotine Polacrilex Lozenge, 4 mg - NDC 72888-187-54 - 81s Carton Label

Drug Facts (continued)

- 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 hiccup, heartburn, nausea or other side effects
- do not use more than 5 lozenges in 8 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, 5 mg
- store at 20° to 25°C (68° to 77°F)
- keep bottle tightly closed and protect from light

TAMPER EVIDENT FEATURES: Do not use if printed seal under cap is broken or missing.

- retain outer carton for full product uses, directions and warnings.

Inactive ingredients

saccharine potassium, colloidal silicon dioxide, flavors, hydroxypropyl cellulose, magnesium stearate, mannitol, potassium bicarbonate, polydioxane, sodium alginate, sodium carbonate, sucralose, and xanthan gum.

Questions? Call 866-488-0312 Monday-Friday 9AM-5PM EST

*This product is not affiliated with, manufactured by, or produced by the makers or owners of Nicorette® Lozenge.

Manufactured by: Rubicon Research Pvt. Ltd
Ambemath, Makarashtra 421 506, India

Distributed by: Advagen Pharma Limited,
606 Plainsboro Road Suite 605,
Plainsboro, NJ, 08538, USA

Rev. 04/23

NDC 72888-187-54
*Compare to the active ingredient in Nicorette® Lozenge

Nicotine Polacrilex Lozenge, 4 mg

STOP SMOKING AID

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 the 2 mg Nicotine Polacrilex Lozenge.

mini Lozenge

81 Lozenges, 4 mg Each
(3 bottles of 27)



TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. Use Strength - Use at least 9 Nicotine Polacrilex Lozenges per day during the first six weeks.
3. Use Long Strength - Use Nicotine Polacrilex Lozenge for the full 12 weeks.
4. Use WISE support program as detailed 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.



Lot:
Exp.:

Drug Facts

Active ingredient (in each lozenge)	Purpose
Nicotine polacrilex; USP, 4 mg	Stop smoking aid

Use

- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

- If you are pregnant or breastfeeding, 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 lozenge 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 (1-800-525-1222).

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:

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. Mimic swallowing. Do not chew or swallow lozenge.

Nicotine Polacrilex Lozenge, 4 mg - NDC 72888-187-55 - 108s Carton Label

Drug Facts (continued)

- 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 8 weeks
- do not use more than one lozenge at a time or continuously use one lozenge after another since this may cause you hiccup, heartburn, nausea or other side effects
- do not use more than 5 lozenges in 8 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, 5 mg
- store at 20° to 25°C (68° to 77°F)
- keep bottle tightly closed and protect from light
- 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

Inactive ingredients
asaccharine potassium, colloidal silicon dioxide, flavor, hydroxypropyl cellulose, magnesium stearate, mannitol, potassium bicarbonate, polydioxane, sodium alginate, sodium carbonate, sucralose, and xanthan gum.

Questions? Call 800-488-0312 Monday-Friday 9AM-5PM EST

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Manufactured by: Rubicon Research Pvt. Ltd
Ambemeth, Maharashtra 421 506, India

Distributed by: Advagen Pharma Limited,
806 Plainsboro Road Suite 005,
Plainsboro, NJ, 08538, USA

Rev. 04/23

NDC 72888-187-55
*Compare to the active ingredient in Nicorette® Lozenge

Nicotine Polacrilex Lozenge, 4 mg

STOP SMOKING AID

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 the 2 mg Nicotine Polacrilex Lozenge.

mini Lozenge

108 Lozenges, 4 mg Each
(4 bottles of 27)



TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. Use 2mg - Use at least 9 Nicotine Polacrilex Lozenges per day during the first 8 weeks.
3. Use 4mg Lozenge - Use Nicotine Polacrilex Lozenges for the full 12 weeks.
4. Use with a support program as detailed 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.



Lot:
Exp.:

Drug Facts

Active ingredient (in each lozenge)	Purpose
Nicotine polacrilex USP, 4 mg	Stop smoking aid

Use

- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

- If you are pregnant or breastfeeding, 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 seizure

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:

Weeks 1 to 5	Weeks 6 to 8	Weeks 9 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.

Nicotine Polacrilex Lozenge, 4 mg - NDC 72888-187-56 - 135s Carton Label

Drug Facts (continued)

- 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 30 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, 5 mg
- store at 20° to 25°C (68° to 77°)
- keep bottle tightly closed and protect from light
- TAMPER EVIDENT FEATURES: Do not use if printed seal under cap is broken or missing.
- retain outer carton for full product uses, directions and warnings.

Inactive ingredients

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

Questions? Call 866-488-0312 Monday-Friday 9AM-5PM EST

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Distributed by: Advagen Pharma Limited,
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Plainsboro, NJ, 08538, USA

Rev: 04/23

NDC 72888-187-56
*Compare to the active ingredient in Nicorette® Lozenge

Nicotine Polacrilex Lozenge, 4 mg

STOP SMOKING AID

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 the 2 mg Nicotine Polacrilex Lozenge.



mini Lozenge

135 Lozenges, 4 mg Each
(5 bottles of 27)



TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. Use Strength - Use at least 9 Nicotine Polacrilex Lozenges per day during the first 6 weeks.
3. Use Long Strength - Use Nicotine Polacrilex Lozenges for the full 12 weeks.
4. Use with a support program as defined 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.

Drug Facts

Active ingredient (in each lozenge) Nicotine polacrilex USP, 4 mg	Purpose Stop smoking aid
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Use

- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

- If you are pregnant or breastfeeding, 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:

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.

NICOTINE MINI

nicotine polacrilex lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72888-186
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: 70097M6130)		
	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 (White to Off-white)	Score	no score
Shape	OVAL	Size	11mm
Flavor	MINT	Imprint Code	A516
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72888-186-53	1 in 1 CARTON	04/14/2023	
1		27 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:72888-186-54	3 in 1 CARTON	04/14/2023	
2		27 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:72888-186-55	4 in 1 CARTON	04/14/2023	
3		27 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:72888-186-56	5 in 1 CARTON	04/14/2023	
4		27 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208875	04/14/2023	

NICOTINE MINI

nicotine polacrilex lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72888-187
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	4 mg
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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 (White to Off-white)	Score	no score
Shape	OVAL	Size	11mm
Flavor	MINT	Imprint Code	A435
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72888-187-53	1 in 1 CARTON	04/14/2023	
1		27 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:72888-187-54	3 in 1 CARTON	04/14/2023	
2		27 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:72888-187-55	4 in 1 CARTON	04/14/2023	
3		27 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:72888-187-56	5 in 1 CARTON	04/14/2023	
4		27 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208875	04/14/2023	

Labeler - Advagen Pharma Limited (051627256)

Establishment

Name	Address	ID/FEI	Business Operations
Rubicon Research Private Limited		677604197	analysis(72888-186, 72888-187) , label(72888-186, 72888-187) , manufacture(72888-186, 72888-187)

Revised: 4/2023

Advagen Pharma Limited