

NICOTINE- nicotine polacrilex gum, chewing
McKesson Corporation dba SKY Packaging

Nicotine Polacrilex Gum Coated Ice Mint 4 mg ANDA204833 - Equate

Drug Facts

Active ingredient (in each chewing piece)

Nicotine Polacrilex 4 mg (nicotine)

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 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, teeth, or jaw problems occur
- 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.

Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap used pieces of gum 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**
- before using this product, read the enclosed User's Guide for complete directions and other important information
- begin using the gum on your quit day
- **if you smoke your first cigarette more than 30 minutes after waking up, use 2 mg nicotine gum**
- **if you smoke your first cigarette within 30 minutes of waking up, use 4 mg nicotine gum** according to the following 12 week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours

- nicotine gum is a medicine and must be used a certain way to get the best results
- chew the gum slowly until it tingles. Then park it between your cheek and gum. When the tingle is gone, begin chewing again, until the tingle returns.
- repeat this process until most of the tingle is gone (about 30 minutes)
- do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece
- to improve your chances of quitting, use at least 9 pieces per day for the first 6 weeks
- if you experience strong or frequent cravings, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you hiccups, heartburn, nausea or other side effects.
- do not use more than 24 pieces a day
- it is important to complete treatment. If you feel you need to use the gum for a longer period to keep from smoking, talk to your health care provider.

Other information

- **each piece contains:** calcium 115 mg, sodium 11 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Inactive ingredients

acacia, acesulfame potassium, butylated hydroxytoluene, carnauba wax, FD&C blue #2, FD&C red #40, FD&C yellow #6, gum base, hydroxypropyl cellulose, hypromellose, natural and artificial cinnamon flavors, sodium bicarbonate, sodium carbonate, sucralose, talc, titanium dioxide and xylitol.

Questions or comments?

Call 1-877-440-7867

Principal Display Panel

*Compare to the active ingredient of Nicorette® Gum

Nicotine Gum

Nicotine Polacrilex Gum USP, 4 mg (nicotine)

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 Nicotine Polacrilex gum, 2 mg

Sugar Free

COATED FRUIT FLAVOR

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit
2. Use Enough - Chew at least 9 pieces of Nicotine Polacrilex Gum per day during the first six weeks
3. Use long enough - Use Nicotine Polacrilex Gum for the full 12 weeks
4. Use with a Support Program as directed in the enclosed User's Guide

To remove the gum, tear off single unit

Peel off backing starting at corner with loose edge

Push gum through foil

- 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

*Nicorette is a trademark of GlaxoSmithKline Consumer Healthcare L.P.

*This product is not affiliated with GlaxoSmithKline Consumer Healthcare, L.P.

BLISTER PACKAGED FOR YOUR PROTECTION. DO NOT USE IF INDIVIDUAL SEALS ARE OPEN OR TORN.

Distributed By:

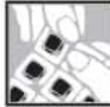
McKesson Corporation dba SKY packaging

4971 Southridge Blvd. Suite 101, Memphis, TN 38141

Package Label

TO INCREASE YOUR SUCCESS IN QUITTING:

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To remove the gum, tear off single unit.



Peel off backing starting at corner with loose edge.



Push gum through foil.

NDC 63739-366-10

*Compare to the active ingredient in Nicorette® Gum



Nicotine Gum

Nicotine polacrilex gum USP, 4 mg (nicotine)
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 Nicotine Polacrilex Gum USP, 2 mg



COATED FRUIT FLAVOR	4	Actual Size
100 Pieces	Sugar Free	mg

Nicotine Gum

Nicotine polacrilex gum USP, 4 mg (nicotine), Stop Smoking Aid

COATED FRUIT FLAVOR	4
100 Pieces	Sugar Free
	mg



4971 Southridge Blvd, Suite 101, Memphis, TN 38141
Distributed By: SKY
Mckesson Corporation dba SKY Packaging



See trade for more details or visit www.nrtethelp.com.

Manufactured by:
P.L. Development
33 Ralph Avenue
Croydon, NY 11726
Packaged by:
P.L. Development
200 Halse Street
Westbury, NY 11590

Nicorette® is a trademark of GlaxoSmithKline Consumer Healthcare, LP.
The product is not affiliated with GlaxoSmithKline Consumer Healthcare, LP.

Questions or comments?
Call 1-877-446-7587

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If you smoke your first cigarette more than 30 minutes after waking up, use 2 mg nicotine gum.
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PLD-4621A 1006491

THAN 30 MINUTES after waking up, use Nicotine Polacrilex Gum USP, 2 mg

■ not for sale to those under 18 years of age
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ALWAYS PACKAGES FOR YOUR PROTECTION. DO NOT USE IF

COATED FRUIT FLAVOR
 100 Pieces Sugar Free
 4 mg

Nicotine polacrilex gum USP, 4 mg
 (Nicotine), Stop Smoking Aid
 Gum

Drug Facts (continued)

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 quit. When the urge to smoke begins, begin chewing gum, until the urge returns. Repeat the process until most of the urge is gone (about 30 minutes). Do not eat or drink for 15 minutes before chewing the nicotine gum, or while chewing a piece.
 ■ To improve your chances of quitting, use at least 8 pieces per day for the first 6 weeks.
 ■ If you experience dizziness or frequent cramping, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you to become dizzy, nauseous, or have other side effects. Do not use more than 24 pieces a day.
 ■ It is important to complete treatment. If you feel you need to use the gum for a longer period to keep from smoking, talk to your health care provider.

Other Information
 ■ Each piece contains calcium 115 mg, sodium 8 mg.
 ■ Store at 20-25°C (68-77°F).
 ■ Do not use more than 24 pieces per day.

Inactive Ingredients
 ■ You get symptoms of nicotine overdose such as nausea, vomiting, diarrhea, regular heartbeat or palpitations occur.
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NDC 63739-368-10
 *Compare to the active ingredient in Nicorette® Gum

Nicotine polacrilex gum USP, 4 mg
 (Nicotine), Stop Smoking Aid
 Gum

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE WITHIN 30 MINUTES OF WAKING UP
 If you smoke your first cigarette MORE

SKY (McKesson) Nicotine 4 mg Fruit Coated

NICOTINE			
nicotine polacrilex gum, chewing			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63739-368
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	
ACACIA (UNII: 5C5403N26O)			
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
FD&C RED NO. 40 (UNII: WZB9127XO A)			
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)			
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)			
SODIUM BICARBONATE (UNII: 8MDF5V39QO)			
SODIUM CARBONATE (UNII: 45P3261C7T)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
XYLITOL (UNII: VCQ006KQ1E)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			

Product Characteristics

Color	YELLOW	Score	no score
Shape	SQUARE	Size	14mm
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63739-368-10	100 in 1 CARTON	04/27/2020	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079038	04/27/2020	

Labeler - McKesson Corporation dba SKY Packaging (140529962)

Revised: 4/2020

McKesson Corporation dba SKY Packaging