

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

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**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:

<b>Weeks 1 to 6</b>	<b>Weeks 7 to 9</b>	<b>Weeks 10 to 12</b>
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:**

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.

NDC 63739-368-10

\*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 mg	Actual Size
100 Pieces	Sugar Free		

# Nicotine Gum

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

COATED FRUIT FLAVOR		4 mg
100 Pieces	Sugar Free	



SKY  
Meknesson Corporation dba SKY Packaging  
Memphis, TN 38141

See inside for more details or visit [www.nicorette.com](http://www.nicorette.com).

Manufactured by:  
P. Development  
350 Highway  
Coppell, TX 75019  
Packaged by:  
P. Development  
350 Highway  
Coppell, TX 75019

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

Call 1-877-753-3835 Monday-Friday 9AM-5PM EST

**Questions or comments?**

gum base, hypoxanthine, sodium benzoate, sodium bicarbonate, sodium carbonate, sucrose, talc, titanium dioxide, xylitol.

**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.
- Keep 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.

**Keep out of reach of children and pets.** Pieces of nicotine gum may have enough residue 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.

**Do not use if you have symptoms of an allergic reaction such as difficulty breathing or rash; dizziness, weakness, and rapid heartbeat.**

**Do not use if you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, or confusion.**



FLD-021A F000791

It is more important than 30 minutes after waking up, use Nicotine Polacrilex Gum USP, 2 mg.

**Nicotine Polacrilex Gum USP, 4 mg (nicotine), Stop Smoking Aid**

**Nicotine Gum**

**Nicotine**

Compare to the active ingredient in Nicorette® Gum

NDC 63739-368-10

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

*If used correctly, Nicotine Gum may reduce the risk of relapse.*

**Drug Facts**

**Active ingredient (in each chewing piece)** Nicotine polacrilex, 4 mg (nicotine). Stop smoking aid.

**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 added to the gum to help you quit smoking. However, the risks to your child from this medicine are not fully known.
- Ask a doctor before use if you have:
  - a sudden-onset chest pain
  - 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 ulcers or diabetes
  - a history of seizures
- Ask a doctor or pharmacist before use if you are:
  - taking 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:
  - you feel dizzy, faint, or your symptoms occur
  - you feel lightheaded or unwell

**Use**

- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking
- Nicotine polacrilex, 4 mg (nicotine).

**Drug Facts (continued)**

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

● Chew the gum slowly until it begins to melt. Then park it between your cheek and gum. When the single is gone, begin chewing again, until the single melts. 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 drowsiness or dizziness, you may use a second piece within the hour. However, do not continuously use one piece after another since this may cause you dizziness, headache, 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 6 mg
- Store at 20° to 25°C (68° to 77°F)
- Grind the gum light

**Inactive ingredients** Acacia, acetaminophen, carboxymethylcellulose, FD&C Yellow #10 lake, FD&C Blue #2 lake, FD&C Red #40, FD&C Yellow #6 lake, flavors.

**Nicotine Gum**

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

COATED FRUIT FLAVOR

100 Pieces	Sugar Free
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**4 mg**

● 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

● All other packages require your protection. Do not use if altered packaging seals are open or torn.

## SKY Nicotine Polacrilex Gum Fruit Flavor

**NICOTINE**  
nicotine polacrilex gum, chewing

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**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63739-368
<b>Route of Administration</b>	ORAL		

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**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	4 mg

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**Inactive Ingredients**

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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**

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	SQUARE	<b>Size</b>	14mm
<b>Flavor</b>	FRUIT	<b>Imprint Code</b>	
<b>Contains</b>			

**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: 10/2023

McKesson Corporation dba SKY Packaging