

NICOTINE POLACRILEX ORIGINAL- nicotine polacrilex gum, chewing
CVS Pharmacy

Nicotine Polacrilex Original 2 mg and 4 mg - CVS

Drug Facts

Active ingredient (in each chewing piece) - 2 mg

Nicotine polacrilex 2 mg (nicotine)

Active ingredient (in each chewing piece) - 4 mg

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 right away.

Directions - 2 mg

- **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 within 30 minutes of waking up**, use 4 mg nicotine gum
- **if you smoke your first cigarette more than 30 minutes after waking up**, use 2 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.

Directions - 4 mg

- **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.
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- 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 - 2 mg

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

Other information - 4 mg

- **each piece contains:** calcium 110 mg, sodium 11 mg
- store at 20 - 25°C (68 - 77°F)
- protect from light

Inactive ingredients - 2 mg

acesulfame potassium, butylated hydroxytoluene, carnauba wax, flavors, gum base, sodium bicarbonate, sodium carbonate, sorbitol and talc.

Inactive ingredients - 4 mg

acesulfame potassium, butylated hydroxytoluene, carnauba wax, D&C yellow #10 lake, FD&C blue #2 lake, FD&C red #40, FD&C yellow #6 lake, flavors, gum base, sodium bicarbonate, sodium carbonate, sorbitol and talc.

Questions or comments?

Call **1-877-440-7867**

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.**

Blister packaged for your protection.

Do not use if individual seals are open or torn.

Principal Display Panel - 2 mg

CVS Health_{TM}

Compare to the active ingredient in Nicorette[®]*

Sugar Free

Nicotine

Gum

2 mg

Nicotine Polacrilex Gum USP,

2 mg (nicotine)

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 Nicotine Polacrilex Gum USP, 4 mg

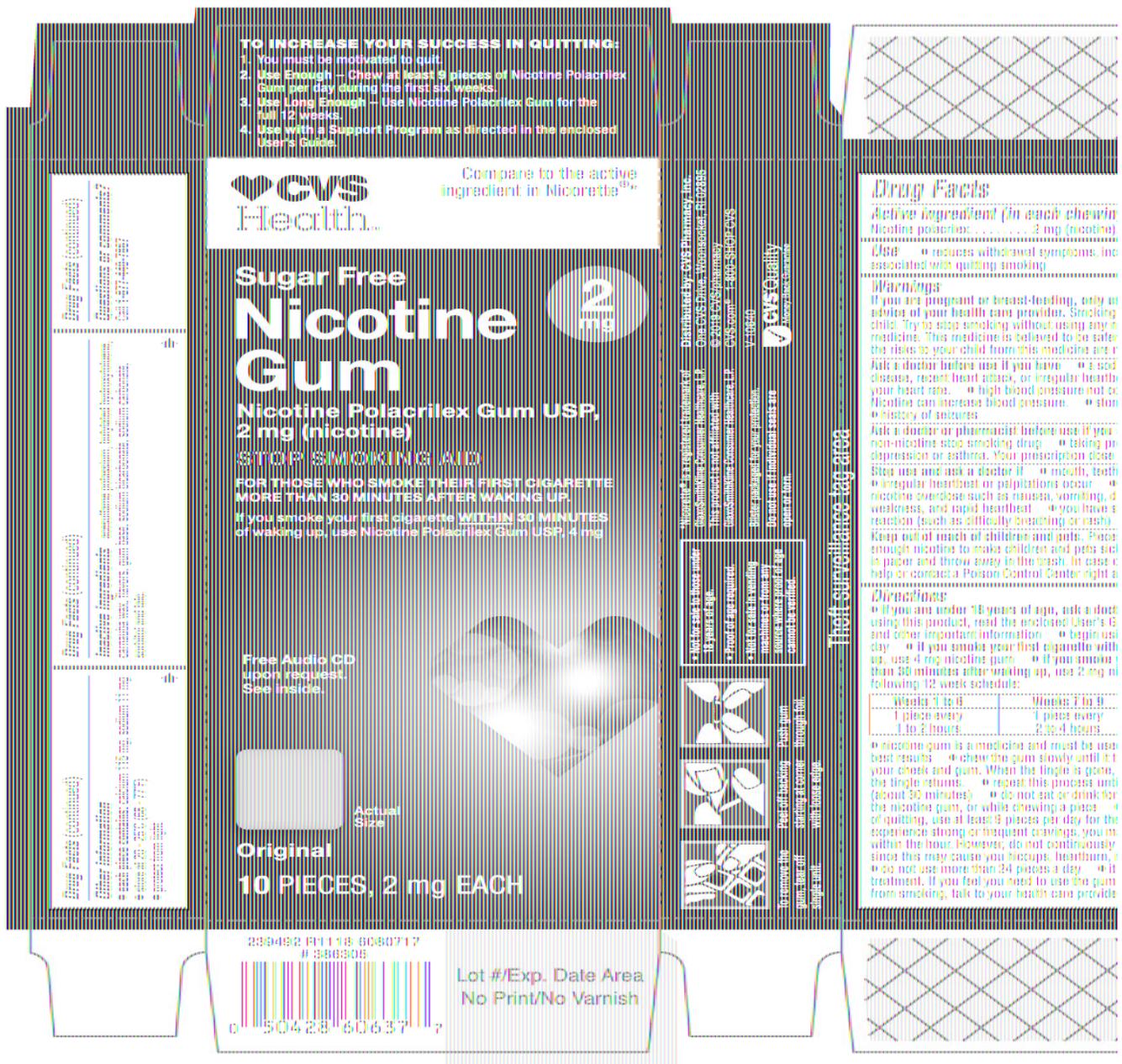
Free Audio CD

upon request.

See inside.

Original

10 PIECES, 2 mg EACH



Principal Display Panel - 4 mg

CVS Health™

Compare to the active ingredient in Nicorette®*

Sugar Free

Nicotine

Gum

4 mg

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

Free Audio CD upon request. See inside.

Original
10 PIECES, 4 mg EACH

Drug Facts (continued)

Questions or comments?
Call 1-877-448-7887

Other Information

- each piece contains: calcium 110 mg, sodium 11 mg
- chew piece carefully; calcium 110 mg, sodium 11 mg
- avoid use with grapefruit juice, grapefruit products, and other products that may interact with nicotine

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. Use **SHOULD** (Chew) 1 to 10 pieces of Nicotine Polacrilex Gum per day during the first 12 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.

CVS Health. Compare to the active ingredient in Nicorette®

Sugar Free Nicotine Gum **4 mg**

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

Free Audio CD upon request. See inside.

Original

10 PIECES, 4 mg EACH

Actual Size



Drug Facts (continued)

Warnings

If you are pregnant or breast-feeding, only use this advice of your health care provider. Smoking can se child. Try to stop smoking without using any nicotine medicine. This medicine is believed to be safer than the risks to your child from this medicine are not fully known.

Ask a doctor before use if you have:

- a sodium-re disease, recent heart attack, or irregular heartbeat. Nic your heart rate.
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- stomach ul
- history of seizures.

Warnings

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Ask a doctor or pharmacist before use if you are:

- taking prescript depression or asthma. Your prescription dose may ne
- taking other stop smoking drug.

Shop use and ask a doctor if:

- you get nicotine overdose such as nausea, vomiting, dizziness, weakness, and rapid heartbeat.
- you have symptom reaction (such as difficulty breathing or rash).

Keep out of reach of children and pets. Pieces of nic enough nicotine to make children and pets sick. Wrap in paper and throw away in the trash. In case of overv help or contact a Poison Control Center right away.

Directions

- If you are under 18 years of age, ask a doctor bef using this product, read the enclosed User's Guide to and other important information.
- Begin using the day.
- If you smoke your first cigarette more than waking up, use 2 mg nicotine gum.
- If you smoke within 30 minutes of waking up, use 4 mg nicotine g following 12 week schedule:

Weeks 1 to 6	Weeks 7 to 9
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours

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- do not use more than 24 pieces a day.
- it is imp treatment. If you feel you need to use the gum for a it from smoking, talk to your health care provider.

Drug Facts (continued)

Other Information

- each piece contains: calcium 110 mg, sodium 11 mg
- chew piece carefully; calcium 110 mg, sodium 11 mg
- avoid use with grapefruit juice, grapefruit products, and other products that may interact with nicotine

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Lot #/Exp. Date Area
No Print/No Varnish

CVS Quality
Heavy Duty Barcodes

CVS Quality
Heavy Duty Barcodes

NICOTINE POLACRILEX ORIGINAL

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-608
Route of Administration	BUCCAL		

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)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SORBITOL (UNII: 506T60A25R)	
TALC (UNII: 7SEV7J4RIU)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-608-15	20 in 1 CARTON	01/01/2014	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69842-608-50	50 in 1 CARTON	01/01/2014	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:69842-608-98	170 in 1 CARTON	01/01/2014	
3		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:69842-608-79	10 in 1 CARTON	01/01/2014	
4		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	ANDA074507	01/01/2014	

NICOTINE POLACRILEX ORIGINAL

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-609
Route of Administration	BUCCAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SORBITOL (UNII: 506T60A25R)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-609-98	170 in 1 CARTON	01/01/2014	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69842-609-15	20 in 1 CARTON	01/01/2014	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:69842-609-50	50 in 1 CARTON	01/01/2014	
3		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:69842-609-79	10 in 1 CARTON	01/01/2014	
4		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	ANDA074707	01/01/2014	

Labeler - CVS Pharmacy (062312574)

Revised: 11/2019

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