

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 (1-800-222-1222) 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 more than 30 minutes of waking up,** use 2 mg nicotine gum
- **if you smoke your first cigarette within 30 minutes after 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.

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.
- 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 - 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 **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal display panel 2 mg

Compare to the active ingredient in Nicorette® Gum

Sugar Free

Nicotine Gum

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 Polacriles Gum USP, 4 mg.

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 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 Gum.

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

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive

Woonsocket, RI 02895

Package label 2 mg

Drug Facts (continued)

Other information

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

Inactive ingredients

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

Questions or comments?

Call 1-877-753-3935
Monday-Friday 9AM-5PM EST



Compare to the active ingredient in Nicorette® Gum*

NDC 69842-608-15

Sugar Free

Nicotine Gum

Nicotine Polacrilex Gum USP, 2 mg (nicotine)

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 Nicotine Polacrilex Gum USP, 4 mg.



Actual Size

Uncoated Original Flavor

20 PIECES, 2 mg EACH

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Push gum through foil.



Peel off backing starting at corner with loose edge.



To remove the gum, tear off single unit.

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.

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Drug Facts

Active ingredient (in each chewing piece)	Purpose
Nicotine polacrilex..... 2 mg (nicotine)	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 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.

CVS HEALTH Sugar Free Nicotine Gum Uncoated Original Flavor

Principal display panel 4 mg

Compare to the active ingredient in Nicorette® Gum*

Sugar Free

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.

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

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive

Woonsocket, RI 02895

Package label 4 mg

minute clinic
START TO STOP
CAN HELP YOU QUIT
CVS.com/StartToStop

Visit MinuteClinic® for personal counseling with a licensed provider.

Compare to the active ingredient in Nicorette® Gum*

Drug Facts (continued)

Other information

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

Inactive ingredients

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, talc

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 Monday-Friday 9AM-5PM EST

CVS Health.

Sugar Free 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.

4 mg

Actual Size

Uncoated Original Flavor

20 PIECES, 4 mg EACH

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

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 ■ proof of age required
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Push gum through foil.

Peel off backing starting at corner with loose edge.

To remove the gum, tear off single unit.

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.

Drug Facts

Active ingredient (in each chewing piece) **Purpose**

Nicotine polacrilex.....4 mg (nicotine)..... Stop smoking aid

Use ■ reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

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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.

#720035

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CVS HEALTH Nicotine Gum Uncoated Original Flavor

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: 7SEV7J4R1U)				
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: 09842-009-79	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: 1/2022

CVS Pharmacy