

NICORETTE FRUIT CHILL- nicotine polacrilex gum, chewing
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Drug Facts

Active ingredient (in each chewing piece)

Nicotine polacrilex (equal to 2 mg nicotine)

Nicotine polacrilex (equal to 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 a 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 2mg nicotine gum
- **if you smoke your first cigarette within 30 minutes of waking up**, use 4mg 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 94 mg, sodium 11 mg
- **(4 mg) each piece contains:** calcium 94 mg, sodium 13 mg
- store at 20 -25°C (68 - 77°F)
- protect from light

Inactive ingredients

each 4 mg piece contains: acacia, acesulfame potassium, carnauba wax, edible ink, flavor, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium bicarbonate, sodium carbonate, sucralose, titanium dioxide, xylitol

Questions or comments?

call toll-free **1-800-419-4766**

TO INCREASE YOUR SUCCESS IN QUITTING:

- You must be motivated to quit.
- **Use Enough** – Chew **at least 9 pieces** of **Nicorette®** gum per day during the first six weeks.
- **Use Long Enough** – Use **Nicorette®** gum for the full 12 weeks.
- **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**

This product is protected in sealed blisters. **Do not use if individual blisters or printed backings are broken, open, or torn.**

Distributed by

GlaxoSmithKline Consumer Healthcare

Warren, NJ 07059

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For more information and for a FREE individualized stop smoking program, please visit www.Nicorette.com or see inside for more details.

Principal Display Panel

NDC 0135-0241-05

Nicorette®

nicotine polacrilex gum, 2mg • stop smoking aid

Gum

Coated

FOR BOLD FLAVOR

Fruit Chill®

2 mg

**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 Nicorette 4 mg Gum

160 PIECES, 2mg EACH

30856XG

NDC 0135-0241-05

gsk

Nicorette[®]

nicotine polacrilex gum, 2 mg • stop smoking aid

Gum



Coated
FOR BOLD FLAVOR

Fruit Chill[®]

160 PIECES, 2 mg EACH



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 Nicorette[®] 4 mg Gum

Principal Display Panel

NDC 0135-0242-05

Nicorette[®]

nicotine polacrilex gum, 4mg • stop smoking aid

Gum

Coated

FOR BOLD FLAVOR

Fruit Chill[®]

4 mg

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 Nicorette 2 mg Gum

160 PIECES, 4 mg EACH

30857XG



Nicorette[®]

nicotine polacrilex gum, 4 mg · stop smoking aid

Gum



Coated
FOR BOLD FLAVOR

Fruit Chill[®]

160 PIECES, 4 mg EACH

4
mg

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 Nicorette[®] 2 mg Gum

NICORETTE FRUIT CHILL

nicotine polacrilex gum, chewing

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0135-0241

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
POLACRILIN (UNII: RCZ785HI7S)	
ACACIA (UNII: 5C5403N26O)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	WHITE	Score	no score
Shape	SQUARE	Size	15mm
Flavor	FRUIT (fruit chill)	Imprint Code	N2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0241-02	1 in 1 CARTON	09/14/2009	
1		100 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0135-0241-03	1 in 1 CARTON	09/14/2009	08/01/2019
2		190 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0135-0241-05	1 in 1 CARTON	09/14/2009	
3		160 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0135-0241-06	1 in 1 CARTON	09/14/2009	
4		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		

5	NDC:0135-0241-08	20 in 1 CARTON; Type 0: Not a Combination Product	09/14/2009	
6	NDC:0135-0241-11	1 in 1 CARTON	09/14/2009	08/01/2018
6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:0135-0241-14	25 in 1 CARTON; Type 0: Not a Combination Product	09/14/2009	08/01/2018
8	NDC:0135-0241-15	8 in 1 PACKAGE	09/14/2009	08/01/2018
8		25 in 1 CARTON; Type 0: Not a Combination Product		
9	NDC:0135-0241-17	2 in 1 PACKAGE	08/01/2014	
9		10 in 1 CARTON		
9		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
10	NDC:0135-0241-18	12 in 1 CARTON	09/01/2018	
10		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
11	NDC:0135-0241-19	18 in 1 CARTON	12/03/2018	
11		10 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
NDA	NDA018612	09/14/2009	

NICORETTE FRUIT CHILL

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0242
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
POLACRILIN (UNII: RCZ785HI7S)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	
ACACIA (UNII: 5C5403N26O)	

Product Characteristics

Color	YELLOW	Score	no score
Shape	SQUARE	Size	15mm
Flavor	FRUIT (fruit chill)	Imprint Code	N4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0242-02	1 in 1 CARTON	09/14/2009	
1		100 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0135-0242-03	1 in 1 CARTON	09/14/2009	08/01/2019
2		190 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0135-0242-05	1 in 1 CARTON	09/14/2009	
3		160 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0135-0242-06	1 in 1 CARTON	09/14/2009	
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9		10 in 1 CARTON		
9		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
10	NDC:0135-0242-18	12 in 1 CARTON	09/01/2018	
10		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
11	NDC:0135-0242-19	18 in 1 CARTON	12/03/2018	
11		10 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
NDA	NDA020066	09/14/2009	

Revised: 11/2018

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC