NICOTINE POLACRILEX- nicotine polacrilex gum, chewing AAFES/Your Military Exchanges

Nicotine Polacrilex Gum Coated Fruit 2mg and 4 mg

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

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 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 piece every	1 piece every
1 to 2 hours	2 to 4 hours	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.

- 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 piece every	1 piece every
1 to 2 hours	2 to 4 hours	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 8 mg
- store at 20 25°C (68 77°F)
- protect from light

Other information - 4 mg

- each piece contains: calcium 115 mg, sodium 8 mg
- store at 20 25°C (68 77°F)
- protect from light

Inactive ingredients- 2mg

acacia, acesulfame potassium, carnauba wax, FD&C blue #2 lake, FD&C red #40, FD&C yellow #6 lake, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, sucralose, talc, titanium dioxide and xylitol.

Inactive ingredients- 4mg

acacia, acesulfame potassium, carnauba wax, D&C yellow #10 lake, FD&C blue #2 lake, FD&C red #40, FD&C yellow #6 lake, flavors, gum base, hydroxypropyl cellulose, magnesium oxide, sodium bicarbonate, sodium carbonate, sucralose, talc, titanium dioxide and xylitol.

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 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 <u>WITHIN</u> 30 MINURES of waking up, use Nicotine Polacrilex Gum USP 4 mg

2 mg

COATED FRUIT

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.
- 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.

Distributed by:

PL Developments

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

Westbury, NY 11590

Principal display panel 4 mg

Compare to the Active Ingredient in Nicorette® Gum*

SUGAR FREE

NICOTINE POLACRILEX GUM USP, 4 MG (NICOTINE)

STOP SMOKING AID

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

If you smoke your first cigarette <u>MORE THAN</u> 30 MINUTES after waking up, use Nicotine Polacrilex Gum USP, 2 mg

4 mg

COATED FRUIT

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.
- 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.

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

Package label 2 mg

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

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.

Compare to the Active Ingredient in Nicorette® Gum*



SUGAR FREE

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



COATED FRUIT



100 PIECES





2 mg

SUGAR FREE

NICOTINE POLACRILEX GUM USP, 2 MG (NICOTINE)

STOP SMOKING AID

OGGLL AN 'AINGISSM SOO Hicks Street Dispripripad by:

"SATISFACTION GLARANTEED OR YOUR MONEY BACK."
Manufactured For Your Military Exchanges

"This product is not menufactured or distributed by GeodGmithGline Consumer Healthcare, L.P., distributor of Miconette* Gum.

Grespons or comments?

PD4C blue 42 Bite, PD8C ned 440, FD8C yellow 46 lake, Devolue Pydrosypropyl cellulose, megmasium cadas, sodium bicarborate, sodium carborate, sucratose, laic, Blantum doodse, syllodi

begin using the gum on your quit day
 if you smokes your first algaretts within 30 minutes of wabling up, use A management

SniOnCOTON:

Before we have a comparable of age, ask a doctor before the comparable of the comparable

Neep out of recent of eliminars and publicace of incidels way.

Neep out of recent of eliminars and pets sick, Wing weat peass of gum for our

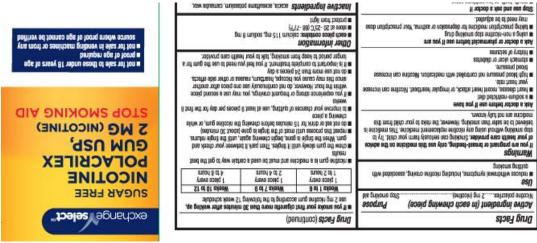
Neep out of most ordinars and pets sick, Wing weat, but out

Online and fine wawy in the result in cree of overdook, Old mode on his

Online and fine and out of the out of the

 in pass symptoms of an alangic reaction (such as difficulty breathing or







Stop use and sak a doctor it

Ask a doctor before use if you have tab betarteen-mulace a m

шверсіра вла пот Ігпуу клюмп.

Drug Facts

EXCHANGE SELECT Nicotine Gum Coated Fruit

Package label 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 enclosed User's Guide.



To remove the gum, tear off single unit.



backing starting at corner with loose edge.



Push gum through foil.

Compare to the Active Ingredient in Nicorette® Gum¹



SUGAR FREE

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



100 PIECES





4 mg

SUGAR FREE

NICOTINE POLACRILEX GUM USP, 4 MG (NICOTINE)

STOP SMOKING AID

Distributed by: 200 Holes Street 300 Holes Street Westbury, NY 11590

"The production and manufactured or challed by Education and the contract of the form of the contract of the challed of the contract of the challed of the c

Questions or comments?

(at 1-87-153-386 Modul-From JMH 978 EST

(40) and attemming protecting waterbooks process. **Streetbooks puriticately**, are action many protecting waterbooks process. **Streetbooks protecting** and one of the object waterbooks and one of the object waterbooks and one object waterbooks and many particular and many belief to the object waterbooks and the object waterbooks waterbooks and the object waterbooks waterbooks waterbooks with the object waterbooks waterbooks waterbooks with the object waterbooks waterbooks waterbooks waterbooks waterbooks with the object waterbooks wate

bugggangh

Diversions

Riversions and Waters of age, ask a deader helicon can
be below using the peaker, then the wickness like it holds to complete
a below using the peaker, then the wickness like it has been about the best and the structural winnershow
as they may be for my over upon the case of them 30 minutes after withing ag,
as it may amond your than degrader man them 30 minutes after withing ag,
and consider your than degrader man of them 30 minutes after the peaker of the peak

coggrey's yearst grape (1-pag-15-25) sifty and/ babes and grow seek in the pray'r in crose of anorgree flag andren pagb as Note set of seeds of disloces and pete. Please at nicelles gum may have a may be asset beau gold. As old for me thick solars to end con my man.

It retained is also been east gold:

usco a medicing with or placed, factors in the contract of the contract o

the seed to be subjected to appreciate in accordance to the procedure accordance.



machines or from any source where proof of age cannot be verified ■ Proof of age required. ■ Not for sale in vending under 18 years of age. ■ Not for sale to those



To the		Other information a such please central ma
hore deadly and more of the angle and the angle set the angle in the angle in the angle and the angle	inge grinke do inged jamag oneg al ingert of to team of the and to set to team 8 moletus enthet education of 1 moletus enthet enthet million million to and sening framente of team sening framente of team sening framente enthet sening framente sening sening framente sening framente sening sening sening sening se	the whole map of webs in the bulk with the bulk will be seen as the see bulk will be seen as the see bulk will be seen as the seen as the bulk will be seen as the seen as the seen as the bulk will be seen as the seen as
Emog group ;	t pece exert	116 2 (1000)
Street storage	QutTusonW	Out Fastorie
Account of evening up, use 4 State of evening up, use 4		





EXCHANGE SELECT Nicotine Gum Coated Fruit

NICOTINE POLACRILEX

nicotine polacrilex gum, chewing

Product Information

XYLITOL (UNII: VCQ006KQ1E)

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55301-503

Route of Administration BUCCAL

Active Ingredient/Active Moiety

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

Inactive Ingredients Ingredient Name Strength **ACACIA** (UNII: 5C5403N260) ACESULFAME POTASSIUM (UNII: 230V73Q5G9) CARNAUBA WAX (UNII: R12CBM0EIZ) FD&C BLUE NO. 2 (UNII: L06K8R7DQK) FD&C RED NO. 40 (UNII: WZB9127XOA) FD&C YELLOW NO. 6 (UNII: H77VEI93A8) HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH) MAGNESIUM OXIDE (UNII: 3A3U0GI71G) **SODIUM BICARBONATE** (UNII: 8MDF5V39QO) **SODIUM CARBONATE** (UNII: 45P3261C7T) SUCRALOSE (UNII: 96K6UQ3ZD4) TALC (UNII: 7SEV7J4R1U) **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP)

Product Characteristics			
Color	brown (light brown)	Score	no score
Shape	SQUARE	Size	14mm

Flavor	FRUIT (coated fruit)	Imprint Code	
Contains			

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55301-503- 44	100 in 1 CARTON	01/01/2014		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
ANDA	ANDA079044	01/01/2014		

NICOTINE POLACRILEX

nicotine polacrilex gum, chewing

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55301-504	
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
ACACIA (UNII: 5C5403N26O)	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
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)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

XYLITOL	(UNII:	VCQ006KQ1E	1
----------------	--------	------------	---

Product Characteristics				
Colorbrown (light tan)Scoreno score				
Shape	SQUARE	Size	14mm	
Flavor	FRUIT (coated fruit)	Imprint Code		
Contains				

l	P	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1	NDC:55301-504- 44	100 in 1 CARTON	01/01/2014			
	1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product				

Marketing I	larketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA079038	01/01/2014		

Labeler - AAFES/Your Military Exchanges (001695568)

Revised: 7/2023 AAFES/Your Military Exchanges