NICORELIEF- nicotine polacrilex gum, chewing
ATLANTIC BIOLOGICALS CORP.

Major Pharmaceuticals Nicorelief® Drug Facts

Active ingredient (in each chewing piece)

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

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 (1-800-222-1222).

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 Nicotine Polacrilex Gum, 2 mg
- if you smoke your first cigarette within 30 minutes of waking up, use Nicotine Polacrilex Gum, 4 mg 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

- each piece contains: calcium 100 mg and sodium 11 mg
- store at 20-25°C (68-77°F)
- protect from light

Inactive ingredients

acesulfame potassium, calcium carbonate, carnauba wax, D&C yellow no. 10, flavors, gum base, sodium bicarbonate, sodium carbonate anhydrous, sorbitol, talc

Questions or comments?

call 1-866-677-7858

Principal Display Panel

COMPARE TO the active ingredient of NICORETTE® GUM

NEW DIRECTIONS FOR USE

Keep Using if You Slip Up and Have a Cigarette

Use Beyond 12 Weeks if Needed to Quit

NICOrelief®

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 NICOrelief®, Nicotine Polacrilex Gum, 2 mg

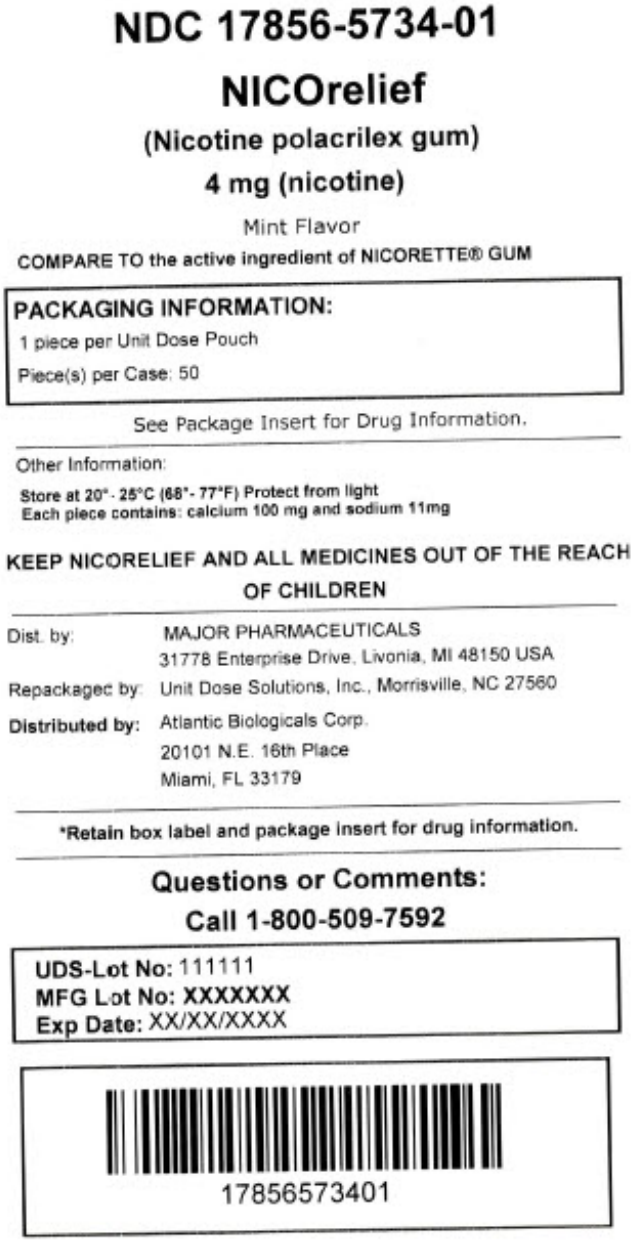
mint flavor

4mg

50 Pieces

actual size

Includes User’s Guide



Free Audio CD upon request. See inside.

NICORELIEF

nicotine polacrilex gum, chewing

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17856-5734(NDC:0904-5737)
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)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SORBITOL (UNII: 506T60A25R)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	YELLOW (light)	**Score**	no score
Shape	RECTANGLE	**Size**	16mm
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-5734-1	1 in 1 POUCH; Type 0: Not a Combination Product	09/20/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078326	04/12/2005	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-5734) , relabel(17856-5734)

Revised: 9/2016 ATLANTIC BIOLOGICALS CORP.