

NICORETTE WHITE ICE MINT- nicotine polacrilex gum, chewing
NICORETTE ORIGINAL- nicotine polacrilex gum, chewing
NICORETTE CINNAMON SURGE- nicotine polacrilex gum, chewing
NICORETTE MINT- nicotine polacrilex gum, chewing
NICORETTE SPEARMINT BURST- nicotine polacrilex gum, chewing
Haleon US Holdings 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 a 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
- **(For Cinnamon Surge)**oral blistering occurs
- 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.
- 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 (White Ice Mint)

- **(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

Other information (Original)

- **each piece contains:** calcium 117 mg, sodium 13 mg
- store at 20 - 25 °C (68 - 77 °F)
- protect from light

Other information (Cinnamon Surge)

- **(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

Other information (Mint)

- **(2 mg) each piece contains:** calcium 94 mg, sodium 13 mg
- **(4 mg) each piece contains:** calcium 94 mg, sodium 14 mg
- store at 20 - 25 °C (68 - 77 °F)

- protect from light

Other information (Spearmint Burst)

- **(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 (White Ice Mint)

each 2 mg piece contains:acesulfame potassium, carnauba wax, edible ink, flavor, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium bicarbonate, sodium carbonate, starch, sucralose, titanium dioxide, xylitol

each 4 mg piece contains:acesulfame potassium, carnauba wax, D&C yellow #10 Al. lake, edible ink, flavor, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium carbonate, starch, sucralose, titanium dioxide, xylitol

Inactive ingredients (Original)

each 2 mg piece contains:flavors, glycerin, gum base, sodium bicarbonate, sodium carbonate, sorbitol

each 4 mg piece contains:D&C yellow #10, flavors, glycerin, gum base, sodium carbonate, sorbitol

Inactive ingredients (Cinnamon Surge)

each 2 mg piece contains:acacia, acesulfame potassium, carnauba wax, edible ink, gum base, hypromellose, magnesium oxide, menthol, natural and artificial cinnamon flavors, peppermint oil, polysorbate 80, sodium bicarbonate, sodium carbonate, sucralose, titanium dioxide, xylitol

each 4 mg piece contains:acacia, acesulfame potassium, carnauba wax, D&C yellow #10 Al. lake, edible ink, gum base, hypromellose, magnesium oxide, menthol, natural and artificial cinnamon flavors, peppermint oil, polysorbate 80, sodium carbonate, sucralose, titanium dioxide, xylitol

Inactive ingredients (Mint)

each 2 mg piece contains:acesulfame potassium, gum base, magnesium oxide, menthol, peppermint oil, sodium bicarbonate, sodium carbonate, xylitol

each 4 mg piece contains:acesulfame potassium, D&C yellow #10 Al. lake, gum base, magnesium oxide, menthol, peppermint oil, sodium carbonate, xylitol

Inactive ingredients (Spearmint Burst)

each 2 mg piece contains:acacia, acesulfame potassium, carnauba wax, edible ink,

flavors, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium bicarbonate, sodium carbonate, sucralose, titanium dioxide, xylitol

each 4 mg piece contains:acacia, acesulfame potassium, carnauba wax, D&C yellow #10 Al. lake, edible ink, flavors, gum base, hypromellose, magnesium oxide, menthol, peppermint oil, polysorbate 80, sodium carbonate, sucralose, titanium dioxide, xylitol

Questions or comments?

call toll-free **1-888-569-1743**

Additional information found on packaging

Includes Quit Support Program

TO INCREASE YOUR SUCCESS IN QUITTING:

1. You must be motivated to quit.
2. **Use Enough**– Chew **at least 9 pieces** of Nicorette gum per day during the first six weeks.
3. **Use Long Enough**– Use Nicorette 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**

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

Nicorette is proud to offer a free individualized quit support program! Visit www.quit.com/join-myquit for details.

Principal Display Panel

NDC 0135-0474-02 HALEON

NICORETTE

nicotine polacrilex gum, 2 mg stop smoking aid

Gum

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

COATED FOR BOLD FLAVOR

100 PIECES, 2 mg EACH

White Ice Mint

824747 Front Label

NDC 0135-0474-02

HALEON

NICORETTE

nicotine polacrilex gum, 2 mg
stop smoking aid
Gum

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

COATED FOR BOLD FLAVOR

100 PIECES, 2 mg EACH

ACTUAL SIZE

White Ice Mint

Principal Display Panel

NDC 0135-0475-02 HALEON

NICORETTE

nicotine polacrilex gum, 4 mg stop smoking aid

Gum

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.

COATED FOR BOLD FLAVOR

100 PIECES, 4 mg EACH

White Ice Mint

824750 Front Label

NDC 0135-0475-02

HALEON

NICORETTE

nicotine polacrilex gum, 4 mg
stop smoking aid
Gum

4mg

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.

COATED FOR
BOLD FLAVOR

100 PIECES, 4 mg EACH



ACTUAL SIZE

White Ice
Mint

Principal Display Panel

NDC 0135-0157-11 HALEON

NICORETTE

nicotine polacrilex gum, 2 mg stop smoking aid

Gum

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

200 PIECES, 2 mg EACH

Original

824754 Front Label

NDC 0135-0157-01

HALEON

NICORETTE

nicotine polacrilex gum, 2 mg
stop smoking aid
Gum

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



ACTUAL SIZE

200 PIECES, 2 mg EACH

Original

Principal Display Panel

NDC 0135-0158-11 HALEON

NICORETTE

nicotine polacrilex gum, 4 mg stop smoking aid

Gum

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.

200 PIECES, 4 mg EACH

Original

824757 Front Label

NDC 0135-0158-11

HALEON

NICORETTE

nicotine polacrilex gum, 4 mg
stop smoking aid
Gum

4mg

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.

200 PIECES, 4 mg EACH



ACTUAL SIZE

Original

Principal Display Panel

NDC 0135-0466-02 HALEON

NICORETTE

nicotine polacrilex gum, 2 mg stop smoking aid

Gum

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

COATED FOR BOLD FLAVOR

100 PIECES

2 mg EACH

Cinnamon Surge

824735 Front Label

NDC 0135-0466-02

HALEON

NICORETTE

nicotine polacrilex gum, 2 mg
stop smoking aid
Gum

2mg

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

COATED FOR
BOLD FLAVOR

100 PIECES, 2 mg EACH

ACTUAL SIZE

Cinnamon
Surge

Principal Display Panel

NDC 0135-0467-02 HALEON

NICORETTE

nicotine polacrilex gum, 4 mg stop smoking aid

Gum

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.

COATED FOR BOLD FLAVOR

100 PIECES

4 mg EACH

Cinnamon Surge

824738 Front Label

NDC 0135-0467-02

HALEON

NICORETTE

nicotine polacrilex gum, 4 mg
stop smoking aid
Gum

4mg

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.

COATED FOR
BOLD FLAVOR

100 PIECES, 4 mg EACH



ACTUAL SIZE

**Cinnamon
Surge**

Principal Display Panel

NDC 0135-0229-05 HALEON

NICORETTE

nicotine polacrilex gum, 2 mg stop smoking aid

Gum

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

170 PIECES, 2 mg EACH

Mint

824762 Front Label

NDC 0135-0229-05

HALEON

NICORETTE

nicotine polacrilex gum, 2 mg
stop smoking aid
Gum

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

170 PIECES, 2 mg EACH



ACTUAL SIZE

Mint

Principal Display Panel

NDC 0135-0230-05 HALEON

NICORETTE

nicotine polacrilex gum, 4 mg stop smoking aid

Gum

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

170 PIECES, 4 mg EACH

Mint

824763 Front Label

NDC 0135-0230-05

HALEON

NICORETTE

nicotine polacrilex gum, 4 mg
stop smoking aid
Gum

4mg

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

170 PIECES, 4 mg EACH



ACTUAL SIZE

Mint

Principal Display Panel

NDC 0135-0532-02 HALEON

NICORETTE

nicotine polacrilex gum, 2 mg stop smoking aid

Gum

2 mg

FOR THOSE WHO SMOKE THEIR FIRST CIGARETTE MORE THAN 30 MINUTES AFTER WAKING UP.

If you smoke your first cigarette **WITHIN30 MINUTES** of waking up, use Nicorette 4 mg Gum

COATED FOR BOLD FLAVOR

100 PIECES, 2 mg EACH

Spearmint Burst with a hint of chamomile

824758 Front Label

NDC 0135-0532-02

HALEON

NICORETTE

nicotine polacrilex gum, 2 mg
stop smoking aid
Gum

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

COATED FOR
BOLD FLAVOR

100 PIECES, 2 mg EACH



ACTUAL SIZE

**Spearmint
Burst**

with a hint of
chamomile

Principal Display Panel

NDC 0135-0533-02 HALEON

NICORETTE

nicotine polacrilex gum, 2 mg stop smoking aid

Gum

4 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 2 mg Gum

COATED FOR BOLD FLAVOR

100 PIECES, 4 mg EACH

Spearmint Burst with a hint of chamomile

824760 Front Label

NDC 0135-0533-02

HALEON

NICORETTE

nicotine polacrilex gum, 4 mg
stop smoking aid
Gum

4mg

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

COATED FOR
BOLD FLAVOR

100 PIECES, 4 mg EACH



ACTUAL SIZE

**Spearmint
Burst**

with a hint of
chamomile

Principal Display Panel

NDC 0135-0355-03 HALEON

NICORETTE

nicotine polacrilex gum, 4 mg stop smoking aid

Gum

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

COATED FOR BOLD FLAVOR

160 PIECES, 4 mg EACH

Spearmint Burst with a hint of chamomile

824761 Front Label



NICORETTE WHITE ICE MINT

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0474
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)	
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	MINT (White Ice Mint)	Imprint Code	N2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0474-01	1 in 1 CARTON	06/29/2009	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0135-0474-02	1 in 1 CARTON	06/29/2009	
2		100 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0135-0474-05	1 in 1 CARTON	06/29/2009	
3		160 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0135-0474-08	20 in 1 CARTON; Type 0: Not a Combination Product	06/29/2009	

5	NDC:0135-0474-14	25 in 1 CARTON; Type 0: Not a Combination Product	06/29/2009	08/01/2018
6	NDC:0135-0474-15	8 in 1 PACKAGE	06/29/2009	08/01/2018
6		25 in 1 CARTON; Type 0: Not a Combination Product		
7	NDC:0135-0474-17	1 in 1 CARTON	06/29/2009	
7		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
8	NDC:0135-0474-18	2 in 1 PACKAGE	08/01/2014	
8		10 in 1 CARTON		
8		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
9	NDC:0135-0474-19	12 in 1 CARTON	09/01/2018	
9		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
10	NDC:0135-0474-20	18 in 1 CARTON	12/03/2018	
10		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	06/29/2009	

NICORETTE WHITE ICE MINT

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0475
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: LMI26O6933)	

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)	

Product Characteristics

Color	white (cream)	Score	no score
Shape	SQUARE	Size	15mm
Flavor	MINT (White Ice Mint)	Imprint Code	N4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0475-01	1 in 1 CARTON	06/29/2009	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0135-0475-02	1 in 1 CARTON	06/29/2009	
2		100 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0135-0475-03	1 in 1 CARTON	06/29/2009	08/01/2019
3		190 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0135-0475-05	1 in 1 CARTON	06/29/2009	
4		160 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:0135-0475-08	20 in 1 CARTON; Type 0: Not a Combination Product	06/29/2009	
6	NDC:0135-0475-14	25 in 1 CARTON; Type 0: Not a Combination Product	06/29/2009	08/01/2018
7	NDC:0135-0475-15	8 in 1 PACKAGE	06/29/2009	08/01/2018
7		25 in 1 CARTON; Type 0: Not a Combination Product		
8	NDC:0135-0475-17	1 in 1 CARTON	06/29/2009	
8		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
9	NDC:0135-0475-18	2 in 1 PACKAGE	08/01/2014	
9		10 in 1 CARTON		
9		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

NDC 0135

10	NDC:0135-0475-19	12 in 1 CARTON	09/01/2018	
10		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
11	NDC:0135-0475-20	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	06/29/2009	

NICORETTE ORIGINAL

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0157
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	white (beige)	Score	no score
Shape	SQUARE	Size	14mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:0135			

1	NDC:0135-0157-07	1 in 1 CARTON	06/29/2009	
1		110 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0135-0157-10	1 in 1 CARTON	06/29/2009	
2		170 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0135-0157-11	1 in 1 CARTON	06/29/2009	
3		200 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0135-0157-12	1 in 1 CARTON	06/29/2009	08/01/2019
4		220 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	06/29/2009	

NICORETTE ORIGINAL

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0158
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)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	white (beige)	Score	no score
Shape	SQUARE	Size	14mm
Flavor		Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0158-07	1 in 1 CARTON	06/29/2009	
1		110 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0135-0158-10	1 in 1 CARTON	06/29/2009	
2		170 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0135-0158-11	1 in 1 CARTON	06/29/2009	
3		200 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0135-0158-12	1 in 1 CARTON	06/29/2009	08/01/2019
4		220 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	06/29/2009	

NICORETTE CINNAMON SURGE

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0466
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	CINNAMON	Imprint Code	N2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0466-01	1 in 1 CARTON	06/29/2009	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0135-0466-02	1 in 1 CARTON	06/29/2009	
2		100 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0135-0466-03	1 in 1 CARTON	06/29/2009	
3		190 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0135-0466-05	1 in 1 CARTON	06/29/2009	
4		160 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:0135-0466-07	1 in 1 CARTON	06/29/2009	
5		40 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:0135-0466-08	20 in 1 CARTON; Type 0: Not a Combination Product	06/29/2009	
7	NDC:0135-0466-14	25 in 1 CARTON; Type 0: Not a Combination Product	06/29/2009	08/01/2018

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018612	06/29/2009	

NICORETTE CINNAMON SURGE

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0467
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)	
ACACIA (UNII: 5C5403N26O)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
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)	

Product Characteristics

Color	white (cream)	Score	no score
Shape	SQUARE	Size	15mm
Flavor	CINNAMON	Imprint Code	N4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0467-01	1 in 1 CARTON	06/29/2009	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0135-0467-02	1 in 1 CARTON	06/29/2009	
		100 in 1 BLISTER PACK; Type 0: Not a Combination		

2		100 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0135-0467-05	1 in 1 CARTON	06/29/2009	
3		160 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0135-0467-07	1 in 1 CARTON	06/29/2009	
4		40 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:0135-0467-08	20 in 1 CARTON; Type 0: Not a Combination Product	06/29/2009	
6	NDC:0135-0467-14	25 in 1 CARTON; Type 0: Not a Combination Product	06/29/2009	08/01/2018

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020066	06/29/2009	

NICORETTE MINT

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0229
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)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	brown (beige)	Score	no score
Shape	SQUARE	Size	14mm

Flavor	MINT	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0229-03	1 in 1 CARTON	06/29/2009	08/01/2019
1		50 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0135-0229-04	1 in 1 CARTON	06/29/2009	08/01/2019
2		110 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0135-0229-05	1 in 1 CARTON	06/29/2009	
3		170 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	06/29/2009		

NICORETTE MINT

nicotine polacrilex gum, chewing

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0230
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)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
ALUMINUM OXIDE (UNII: LMI26O6933)			
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)			
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)			
PEPPERMINT OIL (UNII: AV092KU4JH)			

SODIUM CARBONATE (UNII: 45P3261C7T)

XYLITOL (UNII: VCQ006KQ1E)

Product Characteristics

Color	brown (beige)	Score	no score
Shape	SQUARE	Size	14mm
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0230-03	1 in 1 CARTON	06/29/2009	
1		50 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0135-0230-04	1 in 1 CARTON	06/29/2009	08/01/2019
2		110 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0135-0230-05	1 in 1 CARTON	06/29/2009	
3		170 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	06/29/2009	

NICORETTE SPEARMINT BURST

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0532
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
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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 (beige)	Score	no score
Shape	SQUARE	Size	15mm
Flavor	SPEARMINT	Imprint Code	N2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0532-02	10 in 1 CARTON	09/13/2017	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0135-0532-03	16 in 1 CARTON	09/13/2017	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0135-0532-12	2 in 1 PACKAGE	03/01/2018	
3		10 in 1 CARTON		
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0135-0532-13	12 in 1 CARTON	09/01/2018	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:0135-0532-14	18 in 1 CARTON	12/03/2018	
5		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
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NDA	NDA018612	09/13/2017	
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NICORETTE SPEARMINT BURST

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0533
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)	
ACACIA (UNII: 5C5403N26O)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
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)	

Product Characteristics

Color	yellow	Score	no score
Shape	SQUARE	Size	15mm
Flavor	SPEARMINT	Imprint Code	N4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0533-02	10 in 1 CARTON	09/13/2017	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

2	NDC:0135-0533-12	2 in 1 PACKAGE	03/01/2018	
2		10 in 1 CARTON		
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0135-0533-13	12 in 1 CARTON	09/01/2018	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0135-0533-14	18 in 1 CARTON	12/03/2018	
4		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	09/13/2017	

NICORETTE SPEARMINT BURST

nicotine polacrilex gum, chewing

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0355
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)	
ACACIA (UNII: 5C5403N26O)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
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)

Product Characteristics

Color	yellow	Score	no score
Shape	SQUARE	Size	15mm
Flavor	SPEARMINT	Imprint Code	N4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0355-03	16 in 1 CARTON	09/13/2017	
1		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	09/13/2017	

Labeler - Haleon US Holdings LLC (079944263)

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Haleon US Holdings LLC