

Nicorette® Icy Mint Gum

Nicotine (as resinate) (2mg and 4mg)

What is in this leaflet

1. What Nicorette® Icy Mint Gum is used for
2. How Nicorette® Icy Mint Gum works
3. Before you use Nicorette® Icy Mint Gum
4. How to use Nicorette® Icy Mint Gum
5. While you are using it
6. Side effects
7. Storage and disposal of Nicorette® Icy Mint Gum
8. Product description
9. Manufacturer and Product Registration Holders
10. Date of revision

What Nicorette® Icy Mint Gum is used for

Nicorette® Icy Mint Gum is used to relieve withdrawal symptoms and reduce the cravings for nicotine that you get when you try to stop smoking.

How Nicorette® Icy Mint Gum works

When you stop smoking, your body misses the nicotine that you have been absorbing. You may experience unpleasant feelings and a strong desire to smoke (craving). This indicates you were dependent on nicotine. When you chew Nicorette® Icy Mint Gum, nicotine is released and passes into your body through the lining of your mouth. The nicotine released from the gum is sufficient to relieve the unpleasant withdrawal symptoms such as irritability, restlessness, anxiety, and frustration. It will also help to relieve the sudden intense urge to smoke but Nicorette® Icy Mint Gum will not give you the “buzz” you get from smoking a cigarette.

Before you use Nicorette® Icy Mint Gum

When you must not use it

Do not use

- If you have an allergy to nicotine or any of the other ingredients.
- If you are pregnant, trying to get pregnant or think you may be pregnant.
- If you are breast-feeding. Ask your doctor or pharmacist for advice.

Before you start to use it

Talk to your doctor or pharmacist

- If you have experienced a serious cardiovascular event (heart disease), or hospitalization for a cardiovascular complaint, in the previous 4 weeks (e.g., stroke, myocardial infarction, unstable angina, cardiac arrhythmia, coronary artery bypass graft and angioplasty) or if you suffer from uncontrolled hypertension (high blood pressure).
- If you have stomach ulcer, duodenal ulcer, inflammation of the stomach or inflammation of the oesophagus.
- If you have liver or kidney disease.
- If you have an overactive thyroid gland or have a pheochromocytoma (a tumour of the adrenal gland that can affect blood pressure).
- If you have diabetes, monitor your blood sugar levels more often when starting to use Nicorette® Icy Mint Gum as you may find your insulin or

medication doses require adjustments.

- If you have persistent indigestion or pains in the chest.
- If you have experience of epilepsy and seizures.
- Tell your doctor or pharmacist if the above symptoms persist or worsen, or if you experience new symptoms.

Taking other medicines

Talk to your doctor or pharmacist if you are taking other medicines such as theophylline, clozapine, ropinirole, tacrine, insulin, imipramine, olanzapine, clonipramine, or fluvoxamine. Tell your doctor or pharmacist if you are taking or have recently taken other medicines, even those not prescribed. Stopping smoking may require the dose of these medicines to be adjusted.

How to use Nicorette® Icy Mint Gum

How much to use

Adults:

Number of cigarettes you smoke per day	Dose of Gums
<20 cigarettes	One 2mg gum as required to relieve cravings
≥20 cigarettes	One 4mg gum as required to relieve cravings

Most people use between 8 to 12 gums per day. You must not exceed the following number of gums as stated below in any 24-hour period.

Nicorette® Icy Mint Gum

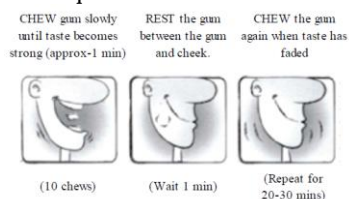
Nicotine (as resinate) (2mg and 4mg)

Dosage Form	Maximum Quantity per day
2mg	30 pieces
4mg	24 pieces

Combination therapy

Highly dependent smokers, smokers who experience “breakthrough” cravings or those who failed with single NRT treatment, can use a flexible smoking cessation format, in combination with patch for fast relief of cravings. Use same dosing recommendation for both patch and gum as per mono therapy. Upon control of cravings, start with tapering patch and gum as directed in mono therapy.

Chew a piece of chewing gum when you have an urge to smoke. The chewing gum is chewed to release nicotine, then tested so that nicotine can be taken in through the lining of the mouth. Nicotine swallowed in the saliva is not beneficial and in excess may irritate your throat or upset your stomach causing e.g., hiccups. To avoid this, refer to the Nicorette® chewing gum technique below.



You should chew only ONE gum at a time. Each gum lasts about 30 minutes. After this time the gum will have lost its strength and you should dispose of it carefully.

Children & adolescents: Not to be administered to persons under 18 years of age without

recommendation from health care professional.

When to use it

The Nicorette® Icy Mint Gum should be used when cigarettes normally would have been smoked or if cravings emerge. Sufficient Nicorette® Icy Mint Gum should be used each day.

How long to use it

We suggest that you use Nicorette® Icy Mint Gum for at least 3 months, 8 to 12 chewing gum per day. Stop smoking completely at the same time in order to increase your chances of success. Regular use beyond 12 months is generally not recommended.

If you forget to use it

Do not take double dose if you forget to use.

If you use too much (overdose)

If you have used more than the recommended dosage, you may experience nausea, vomiting, increased salivation, pain in your abdomen, diarrhea, sweating, headache, dizziness, hearing disturbance or weakness. At higher dose, you will experience low blood pressure, weak and irregular pulse, difficult to breath, collapse and spasm. If you do get any of these effects, seek medical treatment immediately. If excessive amount of nicotine is swallowed, activated charcoal reduces the gastrointestinal absorption of nicotine.

While you are using it

Things you must do

Use the Nicorette® chewing gum technique. Chew only one piece of gum at a time.

Things you must not do

Give this product to children.

Things to be careful of

Avoid swallowing the gum. If a child has used or swallowed the gum, seek medical treatment immediately. Nicotine ingestion by a child may result in severe poisoning.

Side effects

Like all medicines, Nicorette® Icy Mint Gum can cause side effects.

As many of the effects are due to nicotine, they can also occur when nicotine is obtained by smoking.

Effects related to smoking (nicotine withdrawal)

You may experience unwanted effects because you have stopped smoking, or you have reduced the amount of nicotine you are taking. These effects include:

- Dizziness
- Headache
- Irritability or aggression
- Feeling low
- Anxiety Restlessness
- Poor concentration
- Increased appetite or weight gain
- Urge to smoke (craving)
- Sleeplessness or sleep disturbance
- Lowering of heart rate

Side effects of Nicorette® Icy Mint Gum

Most of the undesirable effects reported by the subjects occur during the early phase of treatment and are mainly dose dependent. Irritation in the mouth and throat may be experienced, however most subjects adapt to this with ongoing use. Allergic reactions

Nicorette® Icy Mint Gum

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(including symptoms of anaphylaxis) occur rarely during use of Nicorette® Icy Mint Gum. The chewing gum may stick to and in rare cases, damage dentures.

Side effects observed in post-marketing experience (frequency category estimated from clinical trial):

The commonly reported side-effect is diarrhoea.

Uncommonly reported side effects include fast heartbeat, burping, soreness of the tongue, oral mucosal blistering and exfoliation, prickling/tingling sensation of the mouth, body weakness, chest discomfort and pain, malaise, pain in jaw, abnormal dream, wheezing, voice disorder, shortness of breathing, nasal congestion, oropharyngeal pain, sneezing, throat tightness, increase sweating, skin itching, skin rash, hives, flushing and high blood pressure.

Rarely reported side effects include difficulty swallowing, mouth numbness and retching.

If you notice these or any other unwanted effects not listed in this leaflet, tell your doctor or pharmacist.

When you stop smoking, you may also develop mouth ulcers. The reason why this happens is unclear.

Malaysia:

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my

[Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Nicorette® Icy Mint Gum

Storage

Keep out of reach and sight of children.

Store below 30°C. Protect from light.

Do not use the chewing gum after the 'EXP' date on the box and blister.

Disposal

Dispose of Nicorette® gum sensibly.

Product description

What it looks like

Nicorette® Icy Mint 2mg Gum

Chewing Gum: A square coated white coloured piece with a size of about 15 x 15 x 6 mm.

Nicorette® Icy Mint 4mg Gum

Chewing Gum: A square coated crème coloured piece with a size of about 15 x 15 x 6 mm.

Ingredients

Active Ingredient: *Nicotine*

Inactive Ingredients:

- Nicorette® Icy Mint 2mg Gum

Chewing Gum: Chewing gum base, levomenthol, acesulfame potassium, talc, magnesium oxide (light), xylitol, peppermint oil, sodium carbonate anhydrous, and sodium hydrogen carbonate.

- Nicorette® Icy Mint 4mg Gum

Chewing Gum: Chewing gum base, xylitol, levomenthol, Quinoline yellow E104 Al-lake, acesulfame potassium, magnesium oxide (light), peppermint oil, sodium carbonate anhydrous and talc.

The other ingredients are the ingredients used in the coating of Nicorette® Icy Mint Gums are: Pregelatinized starch, titanium dioxide, hypromellose, water, xylitol, carnauba wax, polysorbate 80, winterfresh, sucralose and quinoline yellow E104 Al-lake (4mg only).

MAL Numbers:

2mg (MAL15045076XRZ)

4mg (MAL15045059XRZ)

Manufacturer

McNeil AB, Norrbroplatsen 2, SE-251 09, Helsingborg, Sweden.

Product Registration Holders

JNTL (MALAYSIA) SDN. BHD.
Lot 3 & 5, Jalan Tandang,
46050 Petaling
Jaya, Selangor, Malaysia.

Consumer Care Centre

Toll Free Number:

1-800-222-565

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