Nicorette® Icy Mint Medicated Chewing Gum

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

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What Nicorette® Icy Mint Gum is used for
Nicorette® Icy Mint Gum is 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. It will also help to stop the craving 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 glands 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 dose require adjustments.
• If you have persistent indigestion or pains in the chest.

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

<table>
<thead>
<tr>
<th>Adults:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Cigarettes you smoke per day</td>
</tr>
<tr>
<td>20 cigarettes or fewer</td>
</tr>
<tr>
<td>More than 20 cigarettes</td>
</tr>
</tbody>
</table>

Most people use between 8 to 12 gums per day. You must not exceed 24 gums per day.

Chew a piece of chewing gum when feeling the need to smoke. The chewing gum is chewed to release nicotine, then rested 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.

The Nicorette® Chewing Gum Technique

When the chewing gum has lost its strength dispose of it carefully, such as back in the hole of the blister.

Children & adolescents: Not to be administered to persons under 18 years of age without recommendation from health care professional.

How long to use it

The full course for using Nicorette® Icy Mint Gum lasts around 16 weeks, from quitting cigarettes to no longer requiring Nicorette® Icy Mint Gum. During that time you should gradually reduce your intake of nicotine, until you can do without it. We suggest that you use Nicorette® Icy Mint Gum for 12 weeks, reducing the number of pieces used in the next 4 weeks.

<table>
<thead>
<tr>
<th>12 weeks</th>
<th>2 weeks</th>
<th>2 weeks</th>
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</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Step 2</td>
<td>Step 3</td>
</tr>
<tr>
<td>Use 8 – 12 pieces of gum per day.</td>
<td>Use 4 – 6 pieces of gum per day.</td>
<td>Use 1 – 3 pieces of gum per day.</td>
</tr>
</tbody>
</table>

Gradually reduce to zero.

*the above program is a guide only.

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 use too much (overdose)
If you have used more than the recommended dosage, you may experience nausea, salivation, pain in your abdomen, diarrhea, sweating, headache, dizziness, hearing disturbance or weakness. If you do get any of these effects, seek medical treatment immediately.

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

Effects of too much nicotine
You may also get these effects if you are not used to inhaling tobacco smoke. These effects include:
- Feeling faint
- Feeling sick (nausea)
- Headache
- Hiccupping (due to excessive swallowing of nicotine)

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 (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):
Common (≥1/100 and <1/10)
Diarrhoea
Uncommon (≥1/1,000 and <1/100)
Palpitations**
Tachycardia**
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 breath**
Nasal congestion
Oropharyngeal pain
Sneezing
Throat tightness
Increase sweating**
Itching**
Rash*
Hives**
Flushing**
High blood pressure**

Rare ≥1/10,000 and <1/1,000
Difficulty in swallowing
Mouth numbness
Retching

*Tightness of jaw and pain in jaw with nicotine gum formulation
**Systemic effects
#Reported as similar or less frequently than placebo

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 calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and disposal of Nicorette® Icy Mint Gum

Storage
Keep out of the reach and sight of children.
Store at or below 30°C. Protect from light.
Do not use the chewing gum after the ‘EXP’ date on the box and blister.

Disposal
Dispose of the Nicorette® Gum sensibly.

Product description

What it looks like
Nicorette® Icy Mint 2mg Chewing Gum: A square coated white coloured piece with a size of about 15 x 15 x 6 mm.
Nicorette® Icy Mint 4mg 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 2 mg 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 4 mg 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, and sucralose and quinoline yellow E 104 Al-lake (4 mg only).

**MAL Numbers:**

2mg: MAL
4mg: MAL

**SIN Numbers:**

2mg: SIN14326P
4mg: SIN14327P

**Manufacturer**

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

**Product Registration Holders**

Johnson & Johnson Sdn Bhd
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**Date of revision**

22nd May 2014