Nicorette® Icy Mint Medicated Chewing Gum

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

WHAT IS NICORETTE® ICY MINT GUM 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.

Advice and support normally improve the success rate.

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.

The benefits of quitting smoking outweigh any risks associated with correctly administered nicotine replacement therapy (NRT).

Nicorette® Icy Mint Gum is not to be administered to persons under 18 years of age without recommendation from health care professional. There is insufficient clinical data from controlled trials to recommend routine use in adolescents under the age of 18.

WHEN NOT TO USE NICORETTE® ICY MINT GUM

Do not use if you have an allergy to nicotine or any of the other ingredients.

WHAT SPECIAL PRECAUTIONS SHOULD YOU TAKE?

Before you start to use it

Talk to your doctor or pharmacist if you have the following conditions:

- Cardiovascular disease. Dependent smokers with a recent myocardial infarction, unstable or worsening angina including Prinzmetal's angina, severe cardiac arrhythmias, recent cerebrovascular accident, and/or who suffer from uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions (such as counselling). If this fails, Nicorette® Icy Mint Gum may be considered but as data on safety in this patient group are limited, initiation should only be under close medical supervision.
- Diabetes mellitus. Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when smoking is stopped, and NRT is initiated as reductions in nicotine-induced catecholamine release can affect carbohydrate metabolism.
- Renal and hepatic impairment. Use with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.
- Phaeochromocytoma and uncontrolled hyperthyroidism. Use with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma as nicotine causes release of catecholamines.
- Gastrointestinal disease. Nicotine may exarcebate symptoms in patients suffering from oesophagitis, gastric or peptic ulcers. Nicotine Replacement Therapy (NRT) preparations should be used with caution in these conditions.

- Epilepsy and seizures. Caution should be exercised in patients with a history of epilepsy or seizures during introduction of nicotine replacement therapy. Tobacco smoke contains substances – including nicotine – which act on brain receptors, and the changes in intake of these when switching from smoked tobacco to nicotine replacement therapy during quitting may affect seizure threshold.

Smokers who wear dentures may experience difficulty in chewing nicotine gum. The chewing gum may stick to, and may in rare cases damage dentures.

Danger in children: Doses of nicotine tolerated by smokers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be handled or ingested by children.

Transferred dependence: Transferred dependence can occur but is unusual and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP1A2. When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, tacrine, clozapine and ropinirole.

If you notice side effects, any other unwanted effects not listed in this leaflet, or have any other questions on the use of this product, stop use and consult your doctor or pharmacist.

Taking other medicines

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However, nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increased pain response (angina-pectoris type chest pain) provoked by adenosine administration.

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.

Pregnancy and breast-feeding

- Women of childbearing potential/ Contraception in males and females
  In contrast to the well-known adverse effects of tobacco smoking on human conception and pregnancy, the effects of therapeutic nicotine treatment are unknown. Thus, whilst to date no specific advice regarding the need for female contraception has been found to be necessary, the most prudent state for women intending to become pregnant to be in is to be both non-smoking, and not using NRT.

  Whilst smoking may have adverse effects on male fertility, no evidence exists that particular contraceptive measures are required during NRT treatment by males.

- Fertility
  In females, tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility. In males, tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity. The specific contribution of nicotine to these effects in humans is unknown.

- Pregnancy
  Smoking during pregnancy is associated with risks such as intra-uterine growth retardation, premature birth or stillbirth. Stopping smoking is the single most effective intervention for

improving the health of both the pregnant smoker and her baby. The earlier abstinence is achieved the better.

Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. Therefore, the pregnant smoker should always be advised to stop smoking completely without using nicotine replacement therapy. The risk of continued smoking may pose greater hazard to the foetus as compared with the use of nicotine replacement products in a supervised smoking cessation programme. Use of Nicorette® Icy Mint Gum by the pregnant smoker should only be initiated after advice from a health care professional.

- Breastfeeding
  Nicotine passes freely into breast milk in quantities that may affect the child even with therapeutic doses. Nicotine should therefore be avoided during breast-feeding. Should smoking cessation not be achieved, use of the Nicorette® Icy Mint Gum by breast feeding smokers should only be initiated after advice from a health care professional.

  Women should take the product as soon as possible after breastfeeding.

Effects on ability to drive or use machines
Nicorette® Icy Mint Gum has no or negligible influence on the ability to drive and use machines.

HOW TO USE NICORETTE® ICY MINT GUM AND HOW MUCH

(A) Monotherapy

How much to use

The initial dosage should be individualized on the basis of the smoker's nicotine dependence. The 4 mg Nicorette® Icy Mint Gum is recommended for smokers who are highly dependent (for example smoking 20 cigarettes or more per day or smoking the first cigarette in the morning 30 minutes or less after waking up). Other smokers should begin treatment with the 2 mg dosage strength.

Number of Cigarettes you smoke per day	Dose of Gums
20 cigarettes or fewer	One 2 mg gum as required to relieve cravings.
More than 20 cigarettes	One 4 mg gum as required to relieve cravings.

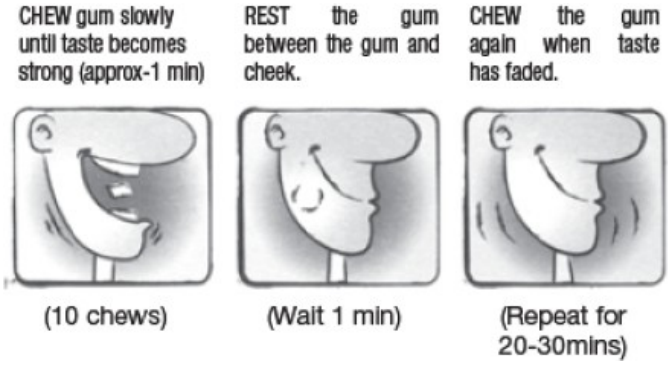
Most people use between 8 to 12 gums per day.
Do not exceed the following quantity in any 24-hour period:
- 2mg: 30 gums
- 4mg: 24 gums

Chew a piece of chewing gum when feeling the need to smoke. Each piece of Nicorette® Icy Mint Chewing Gum should be chewed slowly for approximately 30 minutes, with pauses. The gum should be chewed until a strong taste or mild burning sensation is experienced, then rested between the cheek and gums until the taste and/or sensation have disappeared, then chew again slowly and repeat.

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 stomact 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.

Administration of nicotine should be stopped temporarily if any symptoms of nicotine excess occur. Nicotine intake should be decreased by either lowering dosing frequency or strength if nicotine excess symptoms persist.

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.

12 weeks	2 weeks	2 weeks
Step 1 Use 8 – 12 pieces of gum per day	Step 2 Use 4 – 6 pieces of gum per day.	Step 3 Use 1 – 3 pieces of gum per day.
		Gradually reduce to zero. Treatment should be stopped when the dose is reduced to 1 – 2 Nicorette® Icy Mint Gums per day.

*the above program is a guide only.

Stop smoking completely at the same time in order to increase your chances of success.

To help stay smoke free after treatment, some smokers may need to use the Nicorette® Icy Mint Gum in situations when they are strongly tempted to smoke.

Regular use beyond 12 months is generally not recommended.

(B) Combination Therapy

Highly dependent smokers, smokers who experience 'breakthrough' cravings or those who have failed with single Nicotine Replacement Therapy (NRT) treatment, can use a flexible smoking cessation format, in combination with the patch for fast relief of cravings.

How to combine the use of Nicorette® Invisi Transdermal Patch with Nicorette® Icy Mint Gum 2mg:

- The treatment involves the addition of Nicorette® Icy Mint Gum 2mg to the patch.

- The Nicorette® Invisi Transdermal Patch should be applied daily to an intact area of the skin upon waking and removed at bedtime, and the 2mg Gum should be used as required when cravings occur.

For heavy smokers (more than 15 cigarettes in a 24-hour period):
Use one Nicorette® Invisi Transdermal Patch 25mg/16 hours per day for 12 weeks plus the Nicorette® Icy Mint Gum 2mg. For best results, try to use at least 4 2mg Gums every day. Most people will use 5 – 6 Gums. The maximum number of 2mg Gums that can be taken in conjunction with Nicorette® Invisi Transdermal Patch is 12.

The combination of Nicorette® Icy Mint Gum 2mg and Nicorette® Invisi Transdermal Patch should be used in this way for 12 weeks. After this, you should wean yourself off NRT by either:

1) Using the Nicorette® Invisi Transdermal Patch 15mg/16 hours for 2 weeks, followed by the Nicorette® Invisi Transdermal Patch 10mg/16 hours for 2 weeks, while using the same number of 2mg Gums a day that you have routinely used. Then, when a Patch is no longer needed, gradually reduce the number of 2mg Gums until you no longer need them. OR
2) Stop using the Nicorette® Invisi Transdermal Patch 25mg/16 hours, then gradually reduce the number of 2mg Gums that you use until you no longer need them.

For light smokers (less than 15 cigarettes in a 24-hour period):
Use one Nicorette® Invisi Transdermal Patch 15mg/16 hours per day for 12 weeks plus the Nicorette® Icy Mint Gum 2mg. For best results, try to use at least 4 2mg Gums every day. Most people will use 5 – 6 Gums. The maximum number of 2mg Gums that can be taken in conjunction with Nicorette® Invisi Transdermal Patch is 12.

The combination of Nicorette® Icy Mint Gum 2mg and Nicorette® Invisi Transdermal Patch should be used in this way for 12 weeks. After this, you should wean yourself off NRT by either:

1) Using the Nicorette® Invisi Transdermal Patch 10mg/16 hours for 4 weeks, while using the same number of 2mg Gums a day that you have routinely used. Then, when a Patch is no longer needed, gradually reduce the number of 2mg Gums until you no longer need them. OR
2) Stop using the Nicorette® Invisi Transdermal Patch 15mg/16 hours, then gradually reduce the number of 2mg Gums that you use until you no longer need them.

The Nicorette® Invisi Transdermal Patch should **NOT** be used with Nicorette® Icy Mint Gum 4mg.

Smokers should stop smoking completely during the course of treatment with Nicorette® Icy Mint Gum and Nicorette® Invisi Transdermal Patch.

UNDESIRED 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 of smoking cessation

Regardless of the means used, a variety of symptoms are known to be associated with quitting habitual tobacco use. These include emotional or cognitive effects such as dysphoria or depressed mood; insomnia; irritability, frustration or anger; anxiety; difficulty concentrating, and restlessness or impatience. There may also be physical effects such as decreased heart rate; increased appetite or weight gain, dizziness or presyncopal symptoms, cough, constipation, gingival bleeding or aphthous ulceration, or nasopharyngitis. In addition, and of clinical significance, nicotine cravings may result in profound urges to smoke.

Adverse Drug Reactions

Most of the undesirable effects reported by the subjects occur during the early phase of treatment and are mainly dose dependent.

Allergic reactions (including symptoms of anaphylaxis) occur rarely during use of nicotine products.

Irritation in the mouth and throat may be experienced, however most subjects adapt to this with ongoing use.

The chewing gum may stick to, and may in rare cases damage dentures.

As would be expected, the types of adverse reactions seen for nicotine in clinical trials are similar to those associated with nicotine administered by other means.

Clinical Trial Data

The safety of nicotine from clinical trial data is based on data on a meta-analysis of randomized clinical trials (RCTs) for the treatment of smoking cessation.

Adverse Drug Reactions (ADRs) with oromucosal formulations identified from clinical trials are presented below in Table 1.

Table 1. ADRs Reported with a Frequency ≥1% Identified from Meta-analysis of Clinical Trial Data with Nicotine Oromucosal Formulations

System Organ Class Preferred Term	Active N = 3214 (%)	Placebo N = 2819 (%)
Gastrointestinal Disorders		
Abdominal Pain	1.8	1.2
Dry Mouth	3.2	2.7
Dyspepsia	6.1	3.3
Flatulence	1.8	1.4
Nausea[a]	10.4	5.8
Salivary hypersecretion	2.6	1.0
Stomatitis	2.6	2.0
Vomiting[a]	2.7	1.2
General Disorders and Administration Site Conditions		
Burning sensation*	1.0	0.5
Fatigue[a]	1.0	0.6
Immune System Disorders		
Hypersensitivity[a]	1.4	1.22
Nervous System Disorders		
Headache[a#]	11.5	13.0
Dysgeusia	3.2	2.8
Paraesthesia[a]	1.3	0.8
Respiratory, Thoracic and Mediastinal Disorders		
Cough**	9.3	5.9
Hiccups***	16.4	2.3
Throat irritation**	11.8	4.4

[a]: Systemic effects
*At the application site
** Higher frequency observed in clinical studies with inhaler formulation
***Higher frequency observed in clinical studies with mouth spray formulation

[#]Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the Preferred Term (PT) was identified as a systemic ADR was greater in the active group than the placebo group.

Post Marketing Data

Adverse drug reactions (ADRs) first identified during post-marketing experience with nicotine are presented below. Frequencies are given according to the following convention:

- Very common ≥1/10
- Common ≥1/100 and <1/10
- Uncommon ≥1/1,000 and <1/100
- Rare ≥1/10,000, <1/1,000
- Very rare <1/10,000
- Not known (cannot be estimated from the available data)

Frequency categories are estimated from clinical trials.

- *Frequency category: Common*
  Undesirable Effects: Diarrhoea[#]

- *Frequency category: Uncommon*
  Undesirable Effects: Palpitations**, Tachycardia**, Eructation (belching), Glossitis (inflammation of the tongue), Oral mucosal blistering and exfoliation, Paraesthesia oral[#] (prickling/tingling sensation in the mouth), Asthenia**(abnormal body weakness), Chest discomfort and pain**, Malaise**, Pain in Jaw*, Abnormal dream**,***, Bronchospasm, Dysphonia, Dyspnoea** (shortness of breath), Nasal congestion, Oropharyngeal pain, Sneezing, Throat tightness, Hyperhidrosis**, Pruritus**, Rash**, Urticaria**, Flushing**, Hypertension**

- *Frequency category: Rare*
  Undesirable Effects: Dysphagia (difficulty in swallowing), Hypoaesthesia oral[#] (numbness in the mouth area), Retching

- *Frequency category: Not known*
  Undesirable Effects: Blurred vision, Lacrimation increased, Dry throat, Gastrointestinal discomfort**, Lip pain, Anaphylactic reaction**, Muscle tightness*, Angioedema**, Erythema**, Seizure**

Notes:
*Tightness of jaw and pain in jaw with nicotine gum formulation
**systemic effects
***systemic effect, identified only for formulations administered during night
[#] reported the same or less frequently than placebo.

OVERDOSE

Symptoms of overdose with nicotine from Nicorette® Icy Mint Gum may occur in smokers who have previously had a low nicotine intake from cigarettes or if other sources of nicotine are used concomitantly with Nicorette® Icy Mint Gum.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers) is known to significantly increase tolerability compared with non-smokers. The acute minimum lethal oral dose of nicotine is believed to be 40 to 60 mg in children (oral intake of tobacco from cigarettes) or 0.8 to 1.0 mg/kg in adult non-smokers.

Symptoms of overdose are those of acute nicotine poisoning and include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. At high doses, these symptoms may be followed by hypotension, weak and irregular pulse, breathing difficulties, prostration, circulatory collapse and general convulsions.

Doses of nicotine that are tolerated by adult smokers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

Management of overdose: Administration of nicotine must be stopped immediately and the patient should be treated symptomatically.

The risk of poisoning as a result of swallowing the gum is very small, as absorption in the absence of chewing is slow and incomplete.

If excessive amount of nicotine is swallowed, activated charcoal reduces the gastrointestinal absorption of nicotine.

Keep out of reach of children. In the event of overdose, get medical help right away.

HOW TO STORE NICORETTE® ICY MINT GUM

Storage
Keep out of the reach and sight of children.
Store at or below 30ºC. 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.

WHAT IS IN NICORETTE® ICY MINT GUM

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 2mg 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 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 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 (4mg only).

SIN Numbers:
2mg: SIN14326P

4mg: SIN14327P

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

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