

40 mm

ryze Frosty Mint 2mg Nicotine Gum



1. **Product Name**
ryze Frosty Mint 2mg Nicotine Gum

2. **Name and Strength of Active Ingredient(s)**
Nicotine Resinate 13.3mg equivalent to 2mg nicotine.

3. **Product Description**
White color coated and rectangular shape with Peppermint flavor medicated nicotine chewing gum.

4. **Pharmacodynamics / Pharmacokinetics**
Pharmacodynamics
ATC code: N07B A01
The pharmacological effects of nicotine are well documented. Those resulting from chewing **ryze** Frosty Mint 2mg Nicotine Gum are comparatively small. The response at any one time represents a summation of stimulant and depressant actions from direct, reflex and chemical mediator influences on several organs.
The main pharmacological actions are central stimulation and/or depression; transient hyperpnoea; peripheral vasoconstriction (usually associated with a rise in systolic pressure); suppression of appetite and stimulation of peristalsis.
Pharmacokinetics
Nicotine administered in chewing gums is readily absorbed from the buccal mucous membranes. Demonstrable blood levels are obtained within 5 – 7 minutes and reach a maximum about 30 minutes after the start of chewing. Blood levels are roughly proportional to the amount of nicotine chewed and have been shown never to exceed those obtained from smoking cigarettes.

5. **Indication**
For the relief of nicotine withdrawal symptoms as an aid to smoking cessation.

6. **Posology and Mode of administration**
Adults and Children over 12 years of age
ryze Frosty Mint 2mg Nicotine Gum should be chewed slowly according to the instructions. The strength of gum to be used will depend on the smoking habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2 mg nicotine gum is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.
ryze Frosty Mint 2mg Nicotine Gum should be used whenever the urge to smoke is felt or to prevent cravings in situations where these are likely to occur. Smokers willing or able to stop smoking immediately should initially replace all their cigarettes with the Gum and as soon as they are able, reduce the number of gums used until they have stopped completely. Smokers aiming to reduce cigarettes should use **ryze** Frosty Mint 2mg Nicotine Gum, as needed, between smoking episodes to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. Smoking should be stopped completely.
As soon as they are ready smokers should aim to quit smoking completely. Maximum daily dose: 15 pieces per day.
When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking, but are having difficulty discontinuing **ryze** Frosty Mint 2mg Nicotine Gum are recommended to contact their pharmacist or doctor for advice.
For those using the 4mg gum, switching to the 2 mg gum may be helpful when stopping treatment or reducing the number of gums used each day. The chewing gums should be used whenever there is an urge to smoke according to the “chew and rest” technique described on the pack. After about 30 minutes of such use, the gum will be exhausted. Absorption of nicotine is through the buccal mucosa, any nicotine, which is swallowed being destroyed by the liver.
Sufficient gum should be used each day, usually 8-12. Continue use for up to three months to break the habit of smoking, and then gradually reduce gum use. When daily use is 1-2 gums, use should be stopped. Any spare gum should be retained, as craving

may suddenly return. Not for use by persons under age 18.

7. **Contraindication**
ryze Frosty Mint 2mg Nicotine Gum chewing gum must not be used in:
- hypersensitivity to the active substance or to any of the excipients listed.
- non-smokers, occasional smokers.

8. **Warnings and Precautions**
The risks associated with the use of NRT are substantially outweighed in virtually all circumstances by the well-established dangers of continued smoking.
Patients hospitalised for MI, severe dysrhythmia or CVA who are considered to be haemodynamically unstable should be encouraged to stop smoking with non-pharmacological interventions. If this fails, **ryze** Frosty Mint 2mg Nicotine Gum may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. Once patients are discharged from hospital they can use NRT as normal.
If there is a clinically significant increase in cardiovascular or other effects attributable to nicotine, the gum dose should be reduced or discontinued.
Diabetes: Blood glucose levels may be more variable when stopping smoking, with or without NRT as catecholamines released by nicotine can affect carbohydrate metabolism, so it is important for diabetics to monitor their blood glucose levels more closely than usual while using this product.
Allergic reactions: susceptibility to angioedema and urticaria.
A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:
 - 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.
 - GI Disease: Swallowing of nicotine may exacerbate symptoms in persons suffering from active oesophagitis, oral or pharyngeal inflammation, gastritis, gastric ulcer or peptic ulcer and oral NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.
Danger in small children: Doses of nicotine tolerated by adult and adolescent smokers can produce severe toxicity in small children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. **ryze** Frosty Mint 2mg Nicotine Gum should be disposed of with care.
Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs catalysed by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops this may result in a slower metabolism and a consequent rise in blood levels of such drugs.
Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence. Smokers who wear dentures may experience difficulty in chewing **ryze** Frosty Mint 2mg Nicotine Gum.
Maltitol liquid content: Patients with rare hereditary problems of fructose intolerance should not take this medicine.
Sodium content: To be taken into consideration by patients on a controlled sodium diet.
ryze Frosty Mint 2mg Nicotine Gum should only be used after consulting a physician by certain cardiovascular patient groups where they suffer with uncontrolled hypertension.
This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine

310 mm

12 mm

163 mm

5mm

180 mm

310 mm

and ropinirole.

Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs.

9. **Interactions with other medicaments**
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. Smoking cessation itself may require the adjustment of some drug therapy.

10. **Pregnancy and Lactation**
Pregnancy
Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco.
Stopping completely is by far the best option but NRT may be used in pregnancy as a safer alternative to smoking.
Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be necessary if there is significant nausea and/or vomiting. If patches are used, they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.
Lactation
The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

11. **Undesirable Effects**
NRT may cause adverse reactions similar to those associated with nicotine administered by other means, including smoking. These may be attributable to the pharmacological effects of nicotine, some of which are dose dependent. In relation to this some reported symptoms, such as dizziness, headache and sleep disturbances may be related to withdrawal symptoms associated with abstinence from smoking. Increased frequency of aphthous ulcer may occur after abstinence from smoking.
ryze Frosty Mint 2mg Nicotine Gum in the recommended dose has not been found to cause any serious adverse effects. Excessive consumption of **ryze** Frosty Mint 2mg Nicotine Gum by those who have not been in the habit of inhaling tobacco smoke could possibly lead to nausea, faintness or headache (as may be experienced by such a patient if tobacco smoke is inhaled). Nicotine from the gum may sometimes cause a slight irritation of the throat at the start of treatment and may also cause increased salivation. Excessive swallowing of dissolved nicotine may, at first, cause hiccuping.
Those with a tendency to indigestion may suffer initially from minor degrees of indigestion or heartburn if the 4 mg nicotine gum is used; slower chewing and the use of the 2mg nicotine gum (if necessary, more frequently) will usually overcome this problem.
- | | | |
|-----------|-------------------------|--|
| Rare | Cardiovascular
Other | Atrial fibrillation
allergic reactions such
as angio-oedemic |
| Very rare | | Anaphylactic
reactions |

12. **Overdose**
The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Even small quantities of nicotine may be dangerous in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.
Symptoms
Signs and symptoms of an overdose from nicotine gums would be expected to be the same as those of acute nicotine poisoning, including pallor, cold sweat, salivation, nausea, vomiting, abdominal pain, diarrhoea, headache, dizziness, disturbed hearing and vision, tremor, mental confusion and weakness. Prostration, hypotension, respiratory failure, rapid or weak or irregular pulse, circulatory collapse and convulsions (including terminal convulsions) may ensue with large overdoses.
Management
In the event of an overdose (e.g. too many gum pieces chewed) the user should seek medical attention immediately. All nicotine intake should cease immediately and the patient be treated symptomatically. Artificial respiration with oxygen should be instituted if necessary. Activated charcoal reduces the gastrointestinal absorption of nicotine.

13. **Effects on the ability to Drive and use Machine**
ryze Frosty Mint 2mg Nicotine Gum has no or negligible influence on the ability to drive and use machines.

14. **Instructions for Use**
ryze Frosty Mint 2mg Nicotine Gum should be chewed slowly according to the instructions.
ryze Frosty Mint 2mg Nicotine Gum is suitable for smokers who have their first cigarette of the day more than 30 minutes after waking up.
Behavioural therapy, advice and support will normally improve the success rate.
The nicotine gum should be used whenever there is an urge to smoke according to the “chew and rest” technique described on the pack. After about 30 minutes of such use, the gum will be exhausted. Not more than 15 pieces of the chewing gum may be used each day.
Absorption of nicotine is through the buccal mucosa, any nicotine which is swallowed being destroyed by the liver.

15. **Storage Condition**
Do not store above 30° Celcius

16. **Dosage Forms and Packaging available**
Medicated nicotine gum is packed in the clear blister film. Later the blister was packed in cardboard box containing 12 pieces of chewing gum.

17. **Name and address of manufacturer**
Fertin Pharma A/S, Fertinvej 5,
DK-7100 Vejle, Denmark

18. **Product registration holder**
Aspeya Malaysia Sdn. Bhd.
Level 15, 1 First Avenue,
2A Dataran Bandar Utama,
47800 Petaling Jaya, Selangor, Malaysia

19. **Date of revision**
June 2025



1013318

40 mm

5mm

163 mm

180 mm

12 mm