

RYZE Frosty Mint 2mg Nicotine Gum

Nicotine Resinate 15% w/w

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse.

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What Ryze Frosty Mint 2mg Nicotine Gum is used for

Ryze Frosty Mint 2mg Nicotine Gum is used for the relief of nicotine withdrawal symptoms as an aid to smoking cessation.

How Ryze Frosty Mint 2mg Nicotine Gum works

Ryze Frosty Mint 2mg Nicotine Gum is a nicotine replacement product that helps you to quit smoking or reduce cigarette consumption (smoking reduction).

It is used to treat tobacco addiction by relieving nicotine craving and withdrawal symptoms.

Smokers who are not ready to stop smoking completely can use Ryze Frosty Mint 2mg Nicotine Gum to reduce their cigarette consumption (smoking reduction).

Ryze Frosty Mint 2mg Nicotine Gum may also be used as a temporary replacement for tobacco.

Ryze Frosty Mint 2mg Nicotine Gum 2mg is intended for smokers who were smoking up to/less than 20 cigarettes a day before treatment.

Additional advice and supportive measures can increase the success rate.

What you need to know before using Ryze Frosty Mint 2mg Nicotine Gum

When you must not use it

Do not use Ryze Frosty Mint 2mg Nicotine Gum if

- you are allergic to nicotine or any of the other ingredients of this medicine
- you are a non-smoker
- you are an occasional smoker and smoke one cigarette a day or less

Please ask your doctor if you have any questions about these restrictions on use.

Pregnancy or breastfeeding

It is advised for you to consider quit smoking without using nicotine replacement product.

However, if you are unable to quit without nicotine replacement product, you can use Ryze Frosty Mint 2mg Nicotine Gum nicotine gum as alternative.

Caution should be exercised when consuMint Ryze Frosty Mint 2mg Nicotine Gum nicotine gum.

Please consult your doctor or pharmacist before taking this medicine. They will advise if this treatment is suitable or not for you.

Before you start using 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 phaeochromocytoma 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 nicotine gum as you may find your insulin or medication dose require adjustments.
- If you have persistent indigestion or pains in the chest.

Taking other medicine

Talk to your doctor or pharmacist if you are taking other medicines such as theophylline, clozapine, ropinirole, tacrine, insulin, imipramine, olanzapine, clomipramine, 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 Ryze Frosty Mint 2mg Nicotine Gum

How much to use

The dose is individual and should in general be based on your dependence on tobacco.

The recommended dose is:
Maximum daily dose: 15 pieces per day, where 8 to 12 pieces are regarded as standard, in all other smokers.

However, please consult your doctor before using it. Your doctor will prescribe the appropriate strength and number of gum pieces you must chew everyday.

When to use it

Smoking cessation, quitting smoking immediately. Use 1 piece of Ryze Frosty Mint 2mg Nicotine Gum per Hour.

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Reducing smoking before smoking cessation

Use Ryze Frosty Mint 2mg Nicotine Gum in the period between cigarettes to reduce the craving for cigarettes and prolong the smoking free interval.

Temporary abstinence from smoking Use Ryze Frosty Mint 2mg Nicotine Gum whenever the desire to smoke occur.

How long to use it

Smoking cessation, completely stopping Immediately

Ryze Frosty Mint 2mg Nicotine Gum 2mg Nicotine Gum should be chewed slowly according to the instructions.

If the patient smokes 20 or less cigarettes a day, 2 mg nicotine gum is indicated and 4mg nicotine gum are required for the patient who smoke more than 20 cigarettes per day to meet the withdrawal of the high serum nicotine levels from heavy smoking

When your average daily consumption over the last week has been 1-2 pieces, you should attempt to give up Ryze Frosty Mint 2mg Nicotine Gum nicotine gum.

However, you should keep the chewing gum with you to counteract any new craving for cigarettes.

As soon as they are ready smokers should aim to quit smoking completely. Maximum daily dose: 15 pieces per day.

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.

If you forget to use it

Do not take a double dose to make up for a forgotten dose.

If you use too much (overdose)

The symptoms of an overdose of Ryze Frosty Mint 2mg Nicotine Gum are the same as those of acute nicotine poisoning such as pallor, cold sweat, salivation, nausea, vomiting, abdominal pain, diarrhea, 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.

If you experienced any of the symptoms above, please stop the intake of Ryze Frosty Mint 2mg Nicotine Gum immediately and contact your doctor or pharmacist as soon as possible.

If deemed necessary, you will be given the symptomatic treatment. Activated charcoal helps to reduce the gastrointestinal absorption of nicotine.

While you are using Ryze Frosty Mint 2mg Nicotine Gum

Things you must do

- Tell your doctor if you are taking, have recently taken or might take any other medicines.
- Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

- Do not use more than the recommended amount unless your doctor or pharmacist tells you to.
- Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Things to be careful of

You should stop smoking without support of Ryze Frosty Mint 2mg Nicotine Gum if you:

- recently suffered a myocardial infarction (within the last 3 months)
- have had a bypass operation (angioplasty)
- suffer from unstable or worsening angina (narrowing of the coronary vessels)
- have Prinzmetal's angina (a certain form of angina)
- suffer from uncontrolled or severe cardiac arrhythmia (changes in the way the heart beats)
- recently had a stroke.

If you smoke shortly after a Ryze Frosty Mint 2mg Nicotine Gum you may experience high nicotine concentrations in the blood and corresponding side effects.

Before using Ryze Frosty Mint 2mg Nicotine Gum consider any situations in which you are at risk of reaching for a cigarette without thinking. An existing addiction to nicotine caused by tobacco can continue when nicotine replacement products are used; however, nicotine alone is less harmful than tobacco.

If you are a denture wearer, you may experience difficulties with Ryze Frosty Mint 2mg Nicotine Gum and may be unable to use it.

Ryze Frosty Mint 2mg Nicotine Gum may also loosen dental fillings or. If you have any doubts, consult your dentist.

Side effects

Like all medicines, Ryze Frosty Mint 2mg Nicotine Gum can cause side effects, although not everybody gets them. The side effects are dose dependent.

- Headache
- gastrointestinal symptoms, hiccups, nausea (feeling sick)
- irritations in the mouth or throat, pain in the muscles.

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- Dizziness
- vomiting (being sick).
- Palpitations (fast or irregular heart beat)
- Erythema
- allergic reaction

Meet your doctor or pharmacist right away if you experience any side effects after taking this medicine.

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 Ryze Frosty Mint 2mg Nicotine Gum

Storage

Keep this medicine out of the sight and reach of children.

Do not store above 30 Celcius with the shelf life of 24 months.

Disposal

Do not throw away any medicines via water waste or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

What it looks like

White color coated and rectangular shape with Peppermint flavor medicated nicotine chewing gum.

Ryze Frosty Mint 2mg Nicotine Gum is packed in clear blister film in a cardboard box containing 12 pieces of gum

Ingredients

Active ingredient

Ryze Frosty Mint 2mg Nicotine Gum
2mg
Nicotine resinate (15% w/w):nicotine)

Inactive ingredients

ryze Frosty Mint 2mg Nicotine gum
Gum Center: Gum Base w/BHT,

Xylitol, Calcium Carbonate, Sodium Carbonate Anhydrous, Sodium Hydrogen Carbonate, Acesulfame Potassium, Sucralose, Peppermint, Coolmix, L-Menthol, Talc.

Gum Coat: Maltitol, Titanium Dioxide, Sucralose, Maltitol Liquid, L-Menthol, Peppermint, Coolmix, Carnauba Wax, Talc.

MAL Number

MAL19086004XZ

Manufacturer and Product Registration Holder

Manufacturer

Fertin Pharma A/S, Fertinvej 5,
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Product Registration Holder

Aspeya Malaysia Sdn. Bhd.
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