

## Ryze Frosty Mint Nicotine Gum

### NAME OF THE PRODUCT

Ryze Frosty Mint 4 mg Nicotine gum

### ACTIVE INGREDIENT

Nicotine Polacrilex 26.66mg equivalent to Nicotine 4 mg

### INACTIVE INGREDIENTS

- Ryze Frosty Mint 4mg Nicotine gum: Chewing gum base, Sorbitol, Maltitol, Menthol, Acesulfame potassium, Sucralose, Calcium Carbonate, Tale, Sodium carbonate anhydrous, Sodium bicarbonate, Titanium Dioxide, Peppermint flavour, Gelatin, Carnauba wax.

### PHARMACEUTICAL FORM

White to off-white, coated, square chewing gum pieces.

### PHARMACOLOGY

#### Pharmacodynamics

Pharmacotheapeutic group: Drug used in nicotine dependence. ATC code: N07B A01

A sudden stop of smoking for long term smokers will experience the following withdrawal symptoms: urge or craving to smoke, dysphoria or depressed mood, insomnia, irritability, frustration or aggression, anxiety, difficulty in concentrating, restlessness or impatience, reduced heart rate, increased appetite or increase in weight.

Clinical studies have shown that nicotine replacement products can help smokers quit or reduce their smoking by helping these withdrawal symptoms.

#### Pharmacokinetics

Nicotine administered from a piece of nicotine chewing gum depends on the quantity of nicotine released into the oral cavity and readily absorbed through the oral mucosa. Maximum blood concentration is achieved after 30 minutes of chewing and is proportionate to the concentration 20-30 minutes after smoking a cigarette. The major eliminating organ is the liver. A greatly impaired kidney function is assumed to affect total clearance of nicotine.

### INDICATION

Ryze Frosty Mint Nicotine Gum is used for the treatment of tobacco dependence by relieving nicotine craving and withdrawal symptoms. Facilitating smoking cessation in smokers motivated to quit.

In smokers currently unable to stop smoking abruptly and completely Ryze Frosty Mint Nicotine Gum may also be used initially to reduce cigarette consumption (smoking reduction) in order to achieve smoking cessation.

### DOSAGE AND ROUTE OF ADMINISTRATION

For oral use.

Regular use beyond 12 months is generally not recommended.

#### Adults:

##### Abrupt smoking cessation:

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

The initial dosage should be individualized on the basis of the smoker's nicotine dependence. Ryze Frosty Mint 4 mg Nicotine 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 2mg dosage strength.

The Ryze Frosty Mint Nicotine gum should be used when cigarettes normally would have been smoked or if cravings emerge. Sufficient Ryze Frosty Mint Nicotine gum should be used each day. In order to maximize the chances of success it is important not to underdose. The dosage should be individualized on the basis of the smoker's nicotine dependence.

Dosing regimen: 8 to 12 Ryze Frosty Mint Nicotine gum per day, for at least 3 months. Do not exceed the following number of gums as stated below in any 24-hour period.

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

Smokers should stop smoking completely during the course of treatment with Ryze Frosty Mint Nicotine gum.

Gradual tapering from the Ryze Frosty Mint Nicotine gum should then be initiated. Treatment should be stopped when the dose is reduced to 1 to 2 Ryze gum per day.

Each piece of Ryze Frosty Mint Nicotine gum should be chewed slowly for approximately 30mins, 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.

#### Smoking reduction with subsequent smoking cessation:

Ryze Frosty Mint Nicotine Gum should be used in the time between smoking cigarettes to reduce the urge to smoke and thus to prolong the smoke-free phase. The goal should be to thereby reduce smoking as much as possible.

As soon as one feels able to do so, one should stop smoking completely, but not later than 6 months after starting to use Ryze However, if this is not achieved within 9 months of starting Ryze Frosty Mint Nicotine Gum, a doctor should be consulted.

Please observe the corresponding instructions on use for smoking cessation.

**Children and adolescents:** Do not administer Ryze Frosty Mint Nicotine gum to persons under 18 years of age without recommendation from a health care professional. Ryze Frosty Mint Nicotine gum must not be used in children under 12 years of age.

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.

### CONTRAINDICATION

Hypersensitivity to nicotine or any excipients in the chewing gum. Non-smokers, occasional smokers.

### EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

This product has no or negligible influence on the ability to drive and use machines.

### WARNING AND PRECAUTIONS

Smokers who wear dentures may experience difficulty in chewing Ryze Frosty Mint Nicotine gum. The chewing gum may stick to and may in rare cases damage dentures.

Before taking the Ryze Frosty Mint Nicotine gum, please consult with your healthcare professional if you have the following conditions:

- Serious cardiovascular event (heart disease), or recently hospitalized for a cardiovascular complaint e.g., stroke, myocardial infarction, unstable angina, cardiac arrhythmia, coronary artery bypass graft and angioplasty or suffer from uncontrolled hypertension (high blood pressure)
- Diabetes
- Severe or moderate liver disease
- Severe kidney disease
- An overactive thyroid gland
- A tumor of the adrenal gland (phaeochromocytoma)
- Stomach ulcer
- Oesophagitis
- Ever experienced of epilepsy and seizures
- Hereditary problems of fructose intolerance

If symptoms persist or get worse, or if new symptoms occur, stop use and consult your healthcare professional.

Danger in children: doses of nicotine tolerated by adult or adolescent smokers can produce severe toxicity in children that may be fatal. The product should therefore always be kept out of the sight and reach of children (see section SYMPTOMS AND TREATMENT OF OVERDOSE).

#### **INTERACTION WITH OTHER MEDICAMENTS**

Tell your healthcare professional if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important if you take medicine containing:

theophylline, tacrine, clozapine, ropinirole, imipramine, olanzapine, clomipramine, fluvoxamine, flecainide and pentazocine.

#### **PREGNANCY AND LACTATION**

##### Pregnancy

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 use of 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 Ryze Frosty Mint Nicotine gum by the pregnant smoker should only be initiated after advice from a health care professional.

##### Lactation

Women should take the product just after having breastfeeding. Nicotine passes freely into breast milk in quantities that may affect the child even with therapeutic doses. Ryze Frosty Mint Nicotine gum should therefore be avoided during breast-feeding. Should smoking cessation not be achieved, use of the Ryze Frosty Mint Nicotine gum by breast feeding smokers should only be initiated after advice from a health care professional.

#### **SIDE EFFECTS**

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) can occur rarely during use of Ryze Frosty Mint Nicotine gum.

Like all medicines, Ryze Frosty Mint Nicotine 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

##### Reported Side Effects

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 package insert, tell your healthcare professional.

#### **SYMPTOMS AND TREATMENT OF OVERDOSE**

##### Symptoms of overdose

Symptoms of overdosage with nicotine may occur in smokers who have low nicotine consumption before the treatment or uses other sources of nicotine at the same time.

The symptoms of overdose are those of acute nicotine poisoning and include nausea, vomiting, increased salivation, abdominal pain, diarrhea, 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 small 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. If excessive amount of nicotine is swallowed, activated charcoal reduces the gastrointestinal absorption of nicotine.

##### **Packaging**

Malaysia: Blister pack of 3s, 9s

##### **Storage Condition**

Do not store above 30°C. Protect from light.

Dispose of the chewing gum sensibly.

Keep out of the reach of children.

Jauhi ubat dari kanak-kanak.

##### **Manufacturer:**

Fertin India Pvt. Ltd.

Plot No. L-10 & L-11, Cuncolim Industrial Estate,

Cuncolim, Salcette, Goa- 403 703, India

##### **Product Registration Holders:**

Aspeya Malaysia Sdn. Bhd.

Level 15, 1 First Avenue,

2A Dataran Bandar Utama,

47800 Petaling Jaya

Selangor, Malaysia

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