

Package leaflet: Information for the user

Ryze Mint 2 mg oromucosal powder in pouch

Ryze Mint 4 mg oromucosal powder in pouch

nicotine

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, pharmacist or nurse 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor or pharmacist if you have used <invented name> for more than 6 months.

What is in this leaflet

1. What <invented name> is and what it is used for
2. What you need to know before you use <invented name>
3. How to use <invented name>
4. Possible side effects
5. How to store <invented name>
6. Contents of the pack and other information

1. What <invented name> is and what it is used for

<invented name> contains the active substance nicotine. It relieves craving for nicotine and withdrawal symptoms when you stop smoking and thereby counteracts relapse to smoking in smokers who are motivated to stop.

<invented name> facilitates smoking reduction in smokers who cannot or are unwilling to stop smoking completely.

It is indicated for adults aged 18 years and above.

When you suddenly stop providing nicotine in the form of tobacco to your body, you experience different kinds of discomfort, called withdrawal symptoms. When using <invented name> you can prevent or reduce this discomfort, by continuing to provide a small amount of nicotine to your body during a transitional period.

Advice and support may help you to improve the success rate.

You must talk to a doctor or pharmacist if you have used <invented name> for more than 6 months.

2. What you need to know before you use <invented name>

Do not use <invented name>:

- if you are **allergic** to nicotine or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from severe **heart disease** (e.g. unstable angina pectoris, severe arrhythmia).
- if you have recently had a **heart attack** (within 3 months) or **stroke**

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using <invented name> if you have any of the following. You might still be able to use <invented name>, but need to discuss with your doctor first if you have:

- **chest pain** (unstable angina), or **resting angina**

- a **heart condition** that effects your heart rate or rhythm
- **high blood pressure** which is not being controlled by medicines
- ever had **allergic reactions** that involved swelling of the lips, face and throat (angioedema) or **itchy skin rash** (urticarial). Using nicotine replacement therapy can sometimes trigger this type of reaction
- moderate to severe **liver disease**
- severe **kidney disease**
- **stomach or duodenal ulcer**
- hyperactive **thyroid gland**
- a tumor of the **adrenal gland** (phaeochromocytoma)
- **diabetes** and use insulin as you may require lower doses of insulin
- **inflammation of the gullet** (oesophagitis)

Children and adolescents

Children and adolescents under 18 years of age should not use <invented name>, unless prescribed by a doctor.

A normal dose for adults could seriously poison or even kill a small child. It is therefore important that you keep <invented name> out of the sight and reach of children at all times.

Other medicines and <invented name>

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is specially important if you use other medicines that contain

- theophylline (to treat asthma)
- tacrine (for Alzheimer's disease)
- clozapine (for schizophrenia)
- ropinirole (to treat Parkinson's disease)

<invented name> with food and drink

You should not eat or drink with the pouch in your mouth, since this may decrease the effect of <invented name>.

Acidic drinks (e.g. coffee, fruit juice, or soda) may reduce the uptake of nicotine in the mouth cavity.

To make sure that the best effect will be achieved, you should avoid these drinks within approximately 15 minutes before using <invented name>.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

It is very important to stop smoking during pregnancy since smoking can result in poor growth of your baby. It can also lead to premature births and even stillbirths. Ideally you should stop smoking without the use of medicines containing nicotine. If you cannot manage this, <invented name> should only be used after consulting the healthcare professional who is managing your pregnancy, your doctor, or a doctor that is specialised in helping people quit smoking.

<invented name> should be avoided during breast-feeding as nicotine passes into breast milk and this may affect your child. If your doctor has recommended you to use <invented name> during breast-feeding, it should be taken immediately after breastfeeding and not within two hours before breastfeeding.

Smoking increases the risk of infertility in women and men. The effects of nicotine on fertility is unknown.

Driving and using machines

<invented name> has no or negligible influence on the ability to drive and use machines.

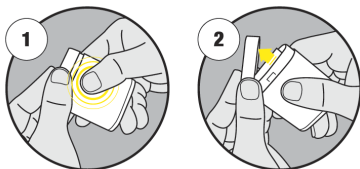
3. How to use <invented name>

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose at the beginning of the treatment is 1 pouch to be used every to every second hour. 8 -12 pouches per day is normally sufficient. Do not use more than 24 pouches per day.

Opening instructions:

1. Press onto the box just below the lid.
2. Lift the lid.



Place the pouch under the upper lip and keep it there for approximately 30 minutes. Occasionally move the pouch around with the tongue.

The onset of effect when using <invented name> is not as fast as when smoking and therefore you cannot expect to experience the same rapid satisfaction as when smoking.

Do not use <invented name> for more than 6 months without consulting your doctor or pharmacist. Regular use of <invented name> for more than 1 year is generally not recommended.

Smoking cessation

The duration of treatment is individual, but should normally continue for at least 3 months. Thereafter the number of pouches per day should be reduced gradually. Therapy should be stopped when the dose has been decreased to 1-2 pouches per day. You may however use a pouch when you are tempted to smoke.

Smoking reduction

<invented name> can be used in between periods of smoking, in order to prolong smoking-free intervals with the intention to reduce smoking as much as possible. If you, after 6 weeks, have not succeeded to cut down the number of cigarettes per day you should seek professional help. You should try to stop smoking as soon as you feel motivated, however no later than 6 months after you started to use <invented name>. If you do not succeed to make a serious attempt to stop smoking within 9 months you should seek professional help.

Children and adolescents

Adolescents under 18 years of age should not use <invented name>, unless prescribed by a doctor.

If you use more <invented name> than you should

Overdose with nicotine could occur if you are only used to low doses of nicotine or if you smoke when using <invented name>.

The symptoms of overdose include nausea, salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, hearing disturbances and pronounced weakness (feeling of weakness). At high doses, these symptoms may be followed by low blood pressure, weak and irregular pulse, difficulty in breathing, extreme tiredness, circulatory collapse and general convulsions.

If a child takes <invented name> or if you use too much nicotine, contact your doctor or the emergency department at the hospital immediately for evaluation of risk and for advice.

If you have any further questions on the use of this medicine, please contact your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

<invented name> may cause the same side effects as nicotine administered in other forms. Side effects are generally dose dependent. See also section “If you use more <invented name> than you should.”

Stop taking <invented name> and contact a doctor or go to the nearest emergency department **immediately** if you experience any of the following symptoms of allergic reactions, which can be serious, such as angioedema. These are rare side effects (may affect up to 1 in 1000 people):

- swollen face, tongue or throat
- difficulty to swallow
- hives and difficulties to breathe

Other side effects that may occur:

Common: may affect up to 1 in 10 people

- dizziness, headache
- gastrointestinal discomfort, hiccups, nausea, vomiting
- irritated mouth or throat

Uncommon: may affect up to 1 in 100 people

- palpitations (feeling fast or irregular heartbeat),
- skin redness and hives

Rare: may affect up to 1 in 1,000 people

- disturbances in heartbeat

Some symptoms such as dizziness, headache and sleeping disturbances may be caused by withdrawal symptoms during smoking cessation and are caused by a decreased supply of nicotine.

Canker sores (painful ulcers in the mucosa of the mouth) can appear when you stop smoking but the connection to smoking cessation is unclear.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store <invented name>

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

Keep the container tightly closed in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the envelope and container after EXP. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What <invented name> contains

- The active substance is nicotine. One pouch contains 2 or 4 mg nicotine.
- The other ingredients are: alginic acid, anhydrous sodium carbonate, copovidone, powdered cellulose, peppermint flavour and neohesperidin dihydrochalcone.

What <invented name> looks like and the contents of the pack

<invented name> is a rectangular pouch filled with powder.

Package size:

20 pouches in a polypropene container with a lid in a laminated aluminium envelope. The pouch is made of non-woven fabric composed of viscose and an acrylic binder.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

[To be completed nationally]

This leaflet was last revised in 2023-10-18