

Package leaflet: Information for the user

Zonnic Mint 2 mg lozenge
Zonnic Mint 4 mg lozenge

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 or 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must contact a doctor if you cannot refrain from smoking after 6 months' treatment with Zonnic Mint.

What is in this leaflet:

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

1. What is Zonnic Mint and what is it used for

The nicotine in Zonnic Mint relieves craving for nicotine and withdrawal symptoms when you stop smoking and counteracts thereby relapse into smoking in smokers who are motivated to stop or to facilitate reduction of smoking for smokers who cannot or are unwilling to stop smoking completely.

When you suddenly stop providing nicotine in the form of tobacco to your body, you will experience different kinds of discomfort, called withdrawal symptoms. By means of Zonnic Mint you can prevent or at least reduce this discomfort, by continuing to provide a small amount of nicotine to your body during a short period of time.

If possible, when stopping smoking, Zonnic should be used in conjunction with a behavioural support program.

2. What you need to know before you use Zonnic Mint

Do not use Zonnic Mint:

- if you are allergic to nicotine or any of the other ingredients of this lozenge (listed in section 6)
- if you are a non-smoker
- *if you are a child under 12 years*

~~Zonnic Mint should not be used by children under 12 years.~~

Warnings and precautions

Talk to your doctor or pharmacist or nurse before using Zonnic Mint if you suffer from the following. You may be able to use Zonnic Mint, but need to discuss with your doctor first if you have:

- severe heart disease (e.g. unstable angina pectoris, severe arrhythmia)
- had a recent (within 3 months) heart attack or stroke

- any heart- or blood circulation disorders
- untreated high blood pressure
- moderate or severe liver disease
- severe kidney disease
- diabetes and use insulin. You may have to change your insuline dose.
- stomach ulcer
- inflammation of the gullet (oesophagitis)
- hyperactive thyroid gland
- tumor of the adrenal gland (phaeochromocytoma)

Children and adolescents

Children under 12 years should not use Zonnic Mint. Adolescents (aged 12-17 years) should not use Zonnic Mint lozenge unless recommended by a doctor.

The correct dose for adults could seriously poison or even kill small children. It is therefore essential that you keep Zonnic Mint lozenge out of sight and reach of children at all times.

Other medicines and Zonnic Mint

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 which contain theophylline, tacrine, clozapine, ropinirole or insulin.

Zonnic Mint with food and drink

You should not eat or drink while you use the lozenge since this may decrease the effect of Zonnic Mint.

Acidic drinks (e.g. fruit juice) influence the uptake of nicotine in the mouth cavity.

To make sure that the best effect will be achieved, you should avoid these drinks approximately 15 minutes prior to using the Zonnic Mint lozenge.

Pregnancy and breast-feeding

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

Zonnic Mint should be avoided during breast-feeding as nicotine is found in breast milk and may effect your child. If your doctor has recommended you to use Zonnic Mint during breast-feeding, the tablet should be taken just after breast-feeding and not during the two hours before breast-feeding.

Driving and using machines

There is no known risks associated with driving or using machinery when the Zonnic Mint lozenge is used according the recommended dose.

Zonnic Mint contains isomalt and maltitol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Zonnic Mint may also have a mild laxative effect. Calorific value 2.3 kcal/g maltitol (or isomalt).

3. How to use Zonnic Mint

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

At the beginning of treatment 1 lozenge may be taken every to every second hour. In most cases, 8 -12 lozenges per day is normally sufficient.

Do not use more than 24 lozenges per day of the 2 mg strength.

Do not use more than 15 lozenges per day of the 4 mg strength.

The strength of lozenge should be chosen considering your nicotine dependence. If you smoke your first cigarette within 30 minutes from awakening in the morning or if you have previously failed to quit smoking using the 2 mg lozenge, the 4 mg lozenge should be chosen. Otherwise the 2 mg should be chosen.

Smoking cessation

Duration of treatment is individual, but it usually takes at least 3 months. Thereafter the nicotine dosage should be reduced gradually. The therapy should be stopped when the dose is at a level of 1-2 lozenges per day. You may however take a lozenge when you are tempted to smoke.

Do not use Zonnic Mint lozenge for more than 6 months unless you have asked your doctor or pharmacist for advice.

Smoking reduction

Zonnic Mint lozenge can be used in between periods of smoking, in order to prolong smoking-free intervals with 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 Zonnic Mint. If you do not succeed to make a serious attempt to stop smoking within 9 months you should seek professional help.

Do not use Zonnic Mint lozenge for more than 6 months without asking your doctor and pharmacist for advice.

Directions for use

1. Place the lozenge in the mouth and let it dissolve.
2. Occasionally move the lozenge from one side of the mouth to the other until it completely dissolves (approx. 10-15 minutes).

Do not chew or swallow the lozenge.

Nicotine effects will appear first after a few minutes.

Therefore you cannot expect the same fast satisfaction as if you smoked. The risk of poisoning is low if the lozenge is accidentally swallowed, as the uptake of nicotine will be slower and to a lesser extent.

If you use more Zonnic Mint than you should

Overdose with nicotine could occur if you smoke simultaneously with using Zonnic Mint lozenge. The symptoms of overdose include nausea, increased saliva, 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 breathing, extreme tiredness, circulatory collapse and general convulsions.

If a child takes Zonnic Mint lozenge or if you take too much nicotine, contact your doctor or the emergency department at the hospital immediately for a risk of judgement.

If you have any further questions regarding this medicine, please contact your doctor or pharmacist or nurse.

4. Possible side effects

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

Zonnic Mint lozenge may cause side effects similar to those associated with nicotine administered in other forms. Side effects are generally dose dependent.

Stop taking Zonnic Mint and contact a doctor or go to your nearest emergency department immediately if you experience any of the following symptoms of allergic reactions, which may be serious, such as angioedema. These are rare side effect (may affect up to 1 in 1,000 people):

- swollen face, tongue or throat

- difficulty swallowing
- hives and breathing difficulties

Other side effects that may occur:

Common (may affect up to 1 in 10 people):

Irritated mouth or throat, during first weeks. Other commonly occurring side effects are dizziness, headache, gastrointestinal discomfort, nausea, vomiting, and hiccups.

Uncommon (may affect up to 1 in 100 people):

Palpitation (feeling fast or irregular heartbeat) and skin redness or rash.

*Rare (may affect up to 1 in 1,000 people):*Disturbances in heartbeat (irregular heartbeat).

Some symptoms such as dizziness, headache and sleeping disturbances may be caused by withdrawal symptoms during smoking cessation and can depend on too low supply of nicotine.

Mouth ulcers can appear when you stop smoking but the connection to the nicotine treatment 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 Zonnic Mint

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

Do not use Zonnic Mint after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in the original package. Sensitive to light.

This medicinal product does not require any special temperature storage conditions.

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 to protect the environment.

6. Contents of the pack and other information

What Zonnic Mint contains

The active substance is nicotine in the form of nicotine ditartrate dihydrate. Zonnic Mint lozenge is available in two strengths: 2 and 4 mg.

The other ingredients are: Isomalt (E953), maltitol liquid (E965), anhydrous sodium carbonate, mint flavour, Brilliant Blue FCF (E133), acesulfame potassium (E950).

Zonnic Mint lozenges are sugarfree.

What Zonnic Mint looks like and the contents of the pack

Zonnic Mint lozenges are blue, round, with an arc shaped imprint, approx. 19 x 7 mm.

Package size:

Blister packs with 12, 24, 72 or 144 lozenges.

The blister pack is composed of aluminium/PVC/PVdC.

All pack sizes may not be marketed.

Marketing Authorisation Holder and Manufacturer

Niconovum AB
Box 31008
SE-200 49 Malmö
Sweden

Manufacturer:
Pierre Fabre Medicament Production
Z.I. de la Coudette
322 90 Aignan
France

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

| | |
|---------|-------------|
| Denmark | Zonnic Mint |
| Finland | Zonnic Mint |
| Norway | Zonnic |
| Sweden | Zonnic Mint |

This leaflet was last revised in

2021-06-04