

Package leaflet: Information for the user

Zonnic Mint 1,5 mg medicated chewing-gum
Zonnic Mint 3 mg medicated chewing-gum
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 of the 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 Zonnic Mint is and what it is 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 get hit by 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.

Advice and support normally improve the success rate.

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 medicine (listed in section 6).
- if you suffer from **severe heart disease** (e.g. unstable angina pectoris, severe arrhythmia).
- if you have recently (within 3 months) had a **heart attack** or **stroke**

Warnings and precautions

Talk to your doctor or pharmacist or nurse before using Zonnic Mint. Contact your doctor if you suffer from:

- **any heart- or blood circulation disorders**
- untreated **high blood pressure**
- severe **liver disease**
- severe **kidney disease**
- **diabetes** and use insulin, see section "Using other medicines"
- **stomach ulcer**
- hyperactive **thyroid gland**
- a tumor of the **adrenal gland** (phaeochromocytoma)

If you have any of these conditions it may not be safe for you to use Zonnic Mint.

Children and adolescents

People **under 18 years of age** should not use Zonnic Mint, unless prescribed by a doctor. Zonnic Mint should not be used by non-smokers.

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

The chewing-gum may stick to dentures and dental bridges and may in rare cases cause their damage.

Other medicines and Zonnic Mint

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important if you use other medicines which **contain teophyllin, takrin, clozapine, ropinirol, flecainide, pentazocine or insulin**.

Zonnic Mint with food and drink

You should not eat or drink while you chew the chewing-gum since this may decrease the effect of Zonnic Mint.

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

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

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 chewing gum 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 is used according to the recommended dose.

Zonnic Mint contains aspartam, maltitol and isomalt

Contains a source of phenylalanin. May be harmful for people with phenylketonuria.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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 one gum may be taken every to every second hour. In most cases, 8 -12 gums per day is normally sufficient. Not more than 24 pieces per day should be used.

The strength of chewing-gum should be chosen considering your nicotine dependence. If you smoke more than 20 cigarettes per day or if you have previously failed to quit smoking using 1.5 mg chewing-gum, the 3 mg gum should be chosen. Otherwise the 1.5 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 pieces of gum per day. You may however take a piece of gum when you are tempted to smoke.

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

Smoking reduction

Zonnic Mint chewing-gum 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 chewing-gum. 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 chewing-gum for more than 6 months without asking your doctor or pharmacist for advice.

Do not chew Zonnic Mint chewing-gum as ordinary chewing-gum. If Zonnic Mint chewing-gum is chewed too quickly and without breaks, nicotine gets released too quickly, which can cause you discomfort (e.g. heartburn and hiccups).

Zonnic Mint chewing-gum chewing technique:

1. Chew a piece of Zonnic Mint chewing-gum until it becomes smooth and the taste becomes strong
2. Rest the piece of chewing gum in your mouth until the taste has faded
3. Chew until the taste becomes strong again
4. Repeat this chewing routine for about 10-30 minutes

Nicotine effects will appear after a few minutes.

Therefore you cannot expect the same fast satisfaction as if you smoked. The risk of poisoning is low if the chewing-gum is accidentally swallowed as the nicotine will then be released slowly and inefficiently.

If you use more Zonnic Mint than you should

Overdose with nicotine could occur if you smoke simultaneously while using Zonnic Mint chewing-gum. 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 chewing-gum 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 may cause side effects similar to those associated with nicotine administered in other forms. Side effects are generally dose dependent.

The **most common side effects** (occur in more than 1 of 100 users) are irritated mouth or throat, during first weeks. Other commonly occurring side effects are dizziness, headache, gastrointestinal discomfort, nausea, vomiting, hiccups and jaw muscle ache.

Less common side effects (occurring in less than 1 of 100 users) are palpitation (feeling fast or irregular heartbeat) and skin redness or rash.

Rare side effects (occurring in less than 1 in 1000 users) are disturbances in heartbeat (irregular heartbeat) and allergic reactions, which can be serious.

If side effects are troublesome or do not go away contact your doctor.

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 this medicine after the expiry date which is stated on the carton and on each unit after “Exp.”. The expiry date refers to the last day of that month.

Do not store above 25 °C. Store in the original package.

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. Zonnic Mint is available in two strengths 1.5 and 3 mg.
- The other ingredients in Zonnic Mint are: Chewing gum base, maltitol (E965), isomalt (E953), flavours, Talcum, magnesiumstearate, silicon dioxide colloidal anhydrous, cellulose (microcrystalline), ascorbyl palmitate (E304), acesulfame potassium (E950), aspartame (E951)
Coating: Isomalt (E953), acacia, titanium dioxide (E171), flavours, macrogol, acesulfame potassium (E950), aspartame (E951)

Zonnic Mint chewing gums are sugar free.

What Zonnic Mint looks like and the contents of the pack

Zonnic Mint is an off-white, coated and circular shaped chewing-gum.

Package size:

20, 100, 200 pieces in aluminium bag

20, 100, 200 pieces in blister pack

Blister pack is composed of aluminium/PVC/PVDC.

Aluminium bag is composed of polyester, aluminium and polyethylene.

Marketing Authorisation Holder and Manufacturer

To be completed nationally.

For Sweden:

Niconovum AB
Järnvägsgatan 13
252 24 Helsingborg

Manufacturer:

Viminco A/S
Lodshusvej 11
DK-4230 Skaelskor
Denmark

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

Sweden: Zonnic Mint 1,5 mg and 3 mg medicated chewing gum

This leaflet was last revised in 2013-12-20