

## Package leaflet: Information for the user

Zonnic 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 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 you use Zonnic Mint:

- **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.

### **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 specially important if you use other medicines which **contain theophyllin, takrin, clozapine, ropinirol, flecainide, pentazocine or insulin**.

### **Zonnic Mint with food and drink**

You should not eat or drink while you use the Zonnic Mint 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 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 affect your child. If your doctor has recommended you to use Zonnic Mint during breast-feeding, the pouch should be taken just after breast-feeding and not during the two hours before breast-feeding.

### **Driving and using machines**

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

### **Zonnic Mint contains aspartam**

Zonnic Mint oromucosal powder in pouch contains a source of phenylalanin. May be harmful for people with phenylketonuria.

## **3. How to use Zonnic Mint**

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

Place a pouch under the upper lip and let it be placed there for approximately 30 minutes. Occasionally move the pouch around with the tongue.

At the beginning of treatment 1 pouch may be taken every to every second hour. In most cases, 8 -12 pouches per day is normally sufficient. Not more than 24 pouches per day should be used.

### *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 pouches per day. You may however take a piece of pouch when you are tempted to smoke.

Do not use Zonnac Mint oromucosal powder in pouch for more than 6 months unless you have asked your doctor or pharmacist for advice.

#### *Smoking reduction*

Zonnac Mint oromucosal powder in pouch 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 Zonnac Mint oromucosal powder in pouch. If you do not succeed to make a serious attempt to stop smoking within 9 months you should seek professional help.

Do not use Zonnac Mint oromucosal powder in pouch for more than 6 months without asking your doctor and pharmacist for advice.

The effects of nicotine appears first after a few minutes. Therefore it can not be expected the feel same fast satisfaction as when smoking. The risk of poisoning is not high if you swallow a pouch by mistake since then a slow and incomplete release of nicotine will appear.

#### **If you use more Zonnac Mint than you should**

Overdose with nicotine could occur if you smoke simultaneously with using Zonnac Mint oromucosal in pouch. 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 Zonnac Mint oromucosal powder in pouch 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 you doctor or pharmacist or nurse.

#### **4. Possible side effects**

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

Zonnac Mint pouch may cause side effects similar to those associated with nicotine administered in other forms. Side effects are generally dose dependent. See also section “If you use more Zonnac Mint than you should.”

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, and hiccups.

**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 store this medicine above 25°C. Store in the original package.

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.

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 oromucosal powder in pouch contains 4 mg nicotine.
- The other ingredients in Zonnic Mint oromucosal powder in pouch are: cellulose (microcrystalline), mint flavour, ascorbyl palmitate (E304), trisodium phosphate, acesulfame potassium (E950), aspartame (E951).

#### **What Zonnic Mint looks like and the contents of the pack**

Zonnic Mint oromucosal powder in pouch is a rectangular, powderfilled pouch.

Package size:

Jar with screw cap in an outer aluminium bag: 20 pouches.

Jar with screw cap: 20 pouches.

Not all pack sizes may be marketed.

#### **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

Apotek, Produktion & Laboratorier (APL)

Celsiusgatan 43

SE-212 14 Malmö

Sweden

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

**This leaflet was last revised in 2016-10-18**