

Package leaflet: information for the user
Nicorette Microtab 2 mg sublingual tablets

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 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. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you cannot refrain from smoking after 6 months' treatment with Nicorette Microtab.

What is in this leaflet

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

1. What Nicorette Microtab is and what it is used for

Nicorette Microtab belongs to a group of medicines which are used to help you stop smoking.

The nicotine in Nicorette Microtab relieves craving for nicotine and withdrawal symptoms when you stop smoking and counteracts thereby relapse into smoking in smokers who are motivated to stop.

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 Nicorette Microtab 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 take Nicorette Microtab

Do not take Nicorette Microtab

- If you are **allergic** (hypersensitive) to nicotine or any of the other ingredients of this medicine (listed in section 6).
- If you are under the age of 12 years
- If you have never smoked

Warnings and precautions

Talk to your doctor before if you suffer from the following. You may be able to have Nicorette Microtab, but need to discuss with your doctor first if you have:

- Recently (within 3 months) had a **heart attack** or **stroke**
- **Chest pain** (unstable angina), or resting angina
- A **heart condition** that affects 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 NRT can sometimes trigger this type of reaction**

- Severe or moderate **liver disease**
- Severe **kidney disease**
- **Diabetes**
- An overactive **thyroid gland**
- A tumour of the **adrenal gland** (phaeochromocytoma)
- **Stomach or duodenal ulcer.**
- **Oesophagitis**
- History of **epilepsy** or **seizures**

Adolescent between **12 and 17 years of age** should only use Nicorette Microtab following advice from a healthcare professional. Nicorette Microtab should not be used by **non-smokers**.

You should stop smoking completely during treatment with Nicorette Microtab.

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

Other medicines and Nicorette Microtab

Tell your doctor or pharmacist if you are taking, have recently taken any other medicines or might take any other medicines. This is especially important if you take medicines containing **theophylline** to treat asthma
tacrine for Alzheimer's disease
clozapine for schizophrenia
ropinirole to treat Parkinson's disease

Pregnancy, breast-feeding and fertility 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 or stillbirths. It is best if you can give up smoking without the use of medicines containing nicotine. If you cannot manage this, Nicorette Microtab 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 specialized in helping people quit smoking.

Nicorette Microtab 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 Nicorette Microtab, the tablet should be taken just after breast-feeding and not during the two hours before breast-feeding.

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

Driving and using machines

No effects on the ability to drive cars or use machines have been observed.

Nicorette Microtab contains 84.5 mg betadex (β -cyclodextrin) in each tablet.

3. How to use Nicorette Microtab

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

The dosage should be chosen with regard to your nicotine-dependence.

At the beginning of the treatment, you can take 1 tablet every 1-2 hours. In most cases, 8-12 tablets a day are sufficient.

At high nicotine dependence or if you smoke more than 20 cigarettes/day start with 2 tablets every 1-2 hours. A maximum of 30 tablets a day should be used.

Nicorette Microtab should be used sublingually, which means that it should be placed under the tongue.

Place the tablet under the tongue and let it dissolve slowly by the saliva. This will take approximately half an hour. Do not chew or swallow the sublingual tablet. However, the risk of poisoning is small, should you happen to swallow the tablet.

The duration of treatment is individual.

The treatment should continue for approximately 2-3 months. Then the nicotine dose should be reduced gradually.

The treatment should be finished when the dose has been reduced to 1-2 tablets a day.

Regular use of Nicorette Microtab for longer than 6 months is normally not recommended. In some cases, a longer treatment period may be necessary to avoid starting smoking again. Remaining tablets should be saved, as craving for smoking may suddenly occur.

If you take more Nicorette Microtab than you should

Overdosing of nicotine may occur if you smoke at the same time as you take Nicorette Microtab.

If a child takes Nicorette Microtab or if you have used more Nicorette Microtab than you should, contact your doctor or go to the nearest hospital **immediately**. Doses of nicotine that are tolerated by adult smokers during treatment may produce severe symptoms of poisoning in **children** and may prove **fatal**.

The symptoms of overdose are nausea, vomiting, too much saliva, stomach pain, diarrhoea, sweating, headache, dizziness, changed hearing, and feeling very weak. 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 you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Nicorette Microtab can give the same side effects as other forms of nicotine. The side effects generally depend on the dose you take.

Effects related to stopping smoking (nicotine withdrawal)

Some of the unwanted effects that you experience when stopping smoking can be withdrawal symptoms due to decreases in nicotine intake.

These effects include:

- Irritability, aggression, impatience or frustration
- Feeling anxious, restless or having difficulty concentrating
- Night time awakening or sleep disturbance
- Increased appetite or weight gain
- Feeling low
- Urges to smoke (*craving*)
- Lowering of heart rate
- Bleeding gums or mouth ulcers
- Dizziness or light-headedness
- Cough, sore throat, stuffy or runny nose
- Constipation

If you notice any of the following serious rare side effects, stop taking Nicorette Microtab and contact a doctor immediately (signs of angioedema):

- swollen face, tongue or pharynx
- difficulty to swallow
- hives and difficulties to breath

Very common: may affect more than 1 in 10 people:

- Cough
- Headache
- Hiccups
- Nausea (feeling sick)
- Throat irritation

Common: may affect up to 1 in 10 people:

- Local effects such as burning sensation, inflammation in the mouth, changes in taste perception
- Dry mouth or increased amounts of saliva
- Feelings of dyspepsia
- Pain or discomfort in tummy (abdomen)
- Vomiting, flatulence or diarrhoea
- Feeling tired (fatigue)
- Hypersensitivity (allergy)

Uncommon: may affect up to 1 in 100 people:

- Effects on the nose such as stuffiness, sneezing and runny nose
- Wheezing (bronchospasm), or feeling like breathing requires more effort than usual (dyspnoea), throat tightness
- Skin flushing (blushing), tingling, or increased sweating
- Oral effects such as mouth tingling, inflammation of the tongue, mouth ulcers, damage to the lining of the mouth, changes in the sound of your voice, pain in the mouth and throat, belching, bleeding gums
- Palpitations (an unusual awareness of your heart beating), increase of heart rate, hypertension
- Rash and/or itching (pruritus, urticaria) of the skin
- Abnormal dream
- Chest discomfort and pain
- Weakness, feeling unwell

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

- Difficulty swallowing, reduced sensations in the mouth
- Retching
- Abnormal heart rhythm

Not known: frequency cannot be estimated from the available data:

- Blurred vision, increased tear production (lacrimation)
- Dry throat, stomach discomfort, pain in the lips
- Redness of the skin
- Allergic reactions including swelling of the face and mouth (angioedema or anaphylaxis)
- Seizure

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nicorette Microtab

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 blister and on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C

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 Nicorette Microtab contains

- The active substance is nicotine. One sublingual tablet contains 2 mg of nicotine as nicotine betadex.
- The other ingredients are: betadex (β -cyclodextrin), crospovidone, magnesium stearate, colloidal anhydrous silica.

What Nicorette Microtab looks like and contents of the pack

The sublingual tablets are white to off-white, flat, round, diameter 6 mm, marked 'NIC' on one side and '2' on the opposite side.

Pack sizes: 20, 30, 90, 100 and 150 sublingual tablets in blister pack with or without carry case.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

<To be completed nationally>

Manufacturer: <To be completed nationally>

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

Finland, France, Sweden	Nicorette Microtab
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This leaflet was last revised in 2023-06-28 <to be completed nationally>