

nicorette®

microtab 2mg sublingual tablet nicotine

What you should know about nicorette® 2mg sublingual tablet
Please read this leaflet carefully before you start using this medicine. It provides useful information on how to use it safely. Keep the leaflet, you might need it again. If you think you are having side-effects, have any questions or are not sure about anything please **ask your doctor, nurse or pharmacist.**

You may experience unpleasant feelings and a strong desire to smoke (craving). This indicates that you were dependent on nicotine. When you use NICORETTE® Microtab, nicotine is released and passes into your body through the lining of your mouth. The nicotine released is sufficient to relieve the unpleasant nicotine withdrawal symptoms. It will also help to stop your craving to smoke but will not give you the "buzz" you get from smoking a cigarette.

The benefits of stopping smoking far outweigh any potential risk from using nicotine from NRT.
It is the toxins in cigarette smoke such as tar, lead, cyanide and ammonia that cause smoking related disease and death, not the nicotine.

2 Before using this medicine

Do not use nicorette® microtab:
■ if you have an allergy to nicotine or any of the other ingredients.

Talk to your doctor, nurse or pharmacist..

■ if you are pregnant or breast-feeding – you may be able to use nicotine replacement therapy (NRT) to help you give up smoking but you should try to give up without it. See "If you are pregnant or breast-feeding" section.

■ if you are in hospital because of heart disease (including heart attack, disorders of heart rate or rhythm, angina, high blood pressure or stroke).
In other heart conditions not requiring you to be in hospital, using NRT is better than continuing to smoke.

■ if you have a stomach ulcer, duodenal ulcer, inflammation of the stomach or inflammation of the oesophagus (passage between the mouth and stomach).

■ if you have liver or kidney disease.

■ if you have an overactive thyroid gland or have a *phaeochromocytoma* (a tumour of the adrenal gland that can affect blood pressure) – your doctor will have told you this.

■ if you have diabetes – monitor your blood sugar levels more often when starting to use NICORETTE® Microtab as you may find your insulin or medication requirements alter.

■ if you are taking other medicines such as theophylline, clozapine or ropinirole. Stopping smoking or cutting down may require the dose of these medicines to be adjusted.

➤ If any of these apply talk to your doctor, nurse or pharmacist.

If you are pregnant or breast-feeding

If you are pregnant: ideally, you should try to give up smoking without NRT. If you can't manage this, you can use NRT as the risks to your baby are far less than smoking, however you should talk to your doctor, nurse or pharmacist for advice. Products that are used intermittently, including NICORETTE® Microtab, may be preferable to nicotine patches. However, patches may be more suitable if you have nausea or sickness. If you do use patches take them off before going to bed at night. **If you are breast-feeding: ideally, you should try to give up smoking without NRT.**

If you can't manage this you are best to use NRT products that are taken intermittently (not patches), however you should talk to your doctor, nurse or pharmacist for advice. Breast-feed just before you use NICORETTE® Microtab to make sure that the baby gets the smallest amount of nicotine possible.

If you do need to use NRT to help you quit, the amount of nicotine that the baby may receive is considerably smaller and less harmful than the second-hand smoke they would inhale if you smoked. Tobacco smoke produces breathing and other problems in babies and children.

Important information about some of the ingredients

- This medicine contains 84.65 mg of cyclodextrin(s) in each sublingual tablet.
- This medicine contains less than 1 mmol sodium (23 mg) in each sublingual tablet, that is to say essentially 'sodium-free'.

3 How and when to use this medicine

How to use nicorette® microtab

Place the microtab under your tongue. Allow it to slowly dissolve (about 30 minutes). This will release nicotine, which you will absorb through the lining of your mouth. NICORETTE® Microtab should NOT be chewed or swallowed.

When to use the nicorette® microtab

Below is the dosage information for the NICORETTE® Microtabs. This shows the number of microtabs you should be taking, when you should take them, how you should take them and the maximum amount

of time you should be using Nicotine Replacement Therapy (NRT) for. Please read the information carefully and then go to the "How to stop smoking: your choice" section, which will help you decide which method to use to give up smoking.

■ The number of NICORETTE® Microtabs you use each day will depend on how many cigarettes you smoked and how strong they were. See dosing information over the page to find out the dose you should use.

Children under 12 years

Do not give this product to children under 12 years.

Adults and Children 12 years and over

Number of Cigarettes you smoke per day	Dose of Microtabs
20 cigarettes or fewer	One microtab to be taken every hour.
More than 20 cigarettes	Two microtabs to be taken every hour.

- Most people take between 8 to 24 microtabs per day.
- Do not take more than 40 microtabs per day. Do not exceed stated dose.
- Children aged 12 and up to 18 years should not use for longer than 12 weeks in total without asking for help and advice from a doctor, nurse or pharmacist.
- Adults aged 18 years and over should not use for more than 9 months in total without asking for help and advice from a doctor, nurse or pharmacist.

How to stop smoking: your choice

Because smoking is an addiction you may find it difficult to give up. From time to time you may still have strong urges to smoke but if you follow these recommendations, you have a good chance of quitting. Some people may find it easier to set a date to quit and **stop smoking immediately.**

Others who are unable or not ready to stop smoking abruptly, may benefit from **gradually reducing** the number of cigarettes they smoke each day until they feel ready to stop completely.

If you are an adult you can follow either one of these options. However children should follow the guide to stopping immediately as the recommended duration of nicotine replacement therapy in children is 12 weeks maximum. The only time children should stop gradually is if they are having a problem stopping immediately and they should talk to their doctor, nurse or pharmacist beforehand.

If you find it hard to stop using NICORETTE® Microtabs, you are worried that you will start smoking again without them or you find it difficult to reduce the number of NICORETTE® Microtabs you are using, talk to your doctor, nurse or pharmacist. Remember NICORETTE® Microtabs are not intended as a substitute for smoking, they are an aid to give up. Use one of the two options which follow.

Stopping Immediately

The idea is to stop smoking immediately and use the microtabs to relieve the

cravings to smoke. After achieving this you then stop using the microtabs. There is a difference in how you stop depending on whether you are aged between 12 -18 years or 18 years and over. Make sure you follow the instructions for the age range applicable to you.

Adults 18 years and over

See the following diagram which shows the basic step by step process. The time given in step 2 is the longest amount of time it should take, and you should try to achieve your move to the next step in the shortest time possible. Make sure you read the instructions for each step in the information which follows.

Preparation	12 weeks (3 months)	Gradually reduce usage
Step 1	Step 2	Step 3

Step 1: Set a date to quit and stop smoking cigarettes.

Step 2: Use 1 or 2 microtabs every hour to relieve your cravings. See "Dosage" section to decide which number of microtabs is suitable for you to use.

➤ Use the microtabs for up to 12 weeks (3 months) to relieve your cravings to smoke.

Step 3: Start reducing the number of tablets you use each day.

Once you reach only one or two tablets each day you should try to stop completely.

➤ If you need to use the microtabs for longer than a total of 9 months, ask your doctor, nurse or pharmacist for advice.

➤ You might feel a sudden craving to smoke long after you have given up smoking and stopped using the NICORETTE® Microtabs. Remember you can use nicotine replacement therapy again if this should happen.

Children aged 12 years and over

See the following diagram which shows the basic step by step process. The time given in steps 2 and 3 are the longest time possible it should take, and you should try to achieve your move to the next step in the shortest amount of time. The total amount of time taken to stop smoking should not exceed 12 weeks. Make sure you read the instructions for each step in the information which follows.

Preparation	8 weeks (2 months)	4 weeks
Step 1	Step 2	Step 3

Step 1: Set a date to quit and stop smoking cigarettes.

Step 2: Use 1 or 2 microtabs every hour to relieve your cravings. See "Dosage" section to decide which number of microtabs is suitable for you to use.

➤ **Use the microtabs for up to 8 weeks (2 months) to relieve your cravings to smoke.**

Step 3: Start reducing the number of tablets you use each day over the next 4 week period. Once you reach only one or two tablets each day you should try to stop completely. You should make sure that you do this within the 4 weeks.

► If you need to use the microtabs for longer than the 12 weeks (3 months), ask your doctor, nurse or pharmacist for advice.

Stopping Gradually

The idea is to start gradually replacing some of your cigarettes with the microtabs. After achieving this you then give up cigarettes completely while using the microtabs. Finally you give up using the microtabs.

There is a difference in how you stop depending on whether you are aged between 12 -18 years or 18 years and over. Make sure you follow the instructions for the age range applicable to you.

Adults 18 years and over

See the following diagram which shows the basic step by step process. The time given for steps 2 and 3 are the longest it should take, and you should try to achieve your move to the next step in the shortest time possible.

Make sure you read the instructions for each step in the information which follows.

Preparation	24 weeks (6 months)	12 weeks (3 months)	4 weeks reduce usage
Step 1	Step 2	Step 3	Step 4

Step 1: Work out how many cigarettes you smoke per day. Set a date to start reducing the number of cigarettes you smoke.

Step 2: Start reducing. Over the next few months, reduce the number of cigarettes you smoke by using 1 or 2 NICORETTE® Microtabs every hour to relieve your cravings. See “Dosage” section to decide which number of microtabs is suitable for you to use.

- **If after 6 weeks you have not reduced the number of cigarettes you smoke, ask your doctor, nurse or pharmacist for advice.**
- **You should aim to stop smoking completely by six months from the beginning of treatment.**

Step 3: Stop smoking. Cut out all cigarettes and continue using the microtabs for up to 3 months to relieve your cravings to smoke.

Step 4: Start reducing the use of the microtabs. You should try to use fewer microtabs each day. When you are using only one or two microtabs per day, you should stop completely.

- **If you need to use the product for longer than 9 months, ask your doctor, nurse or pharmacist for advice.**
- **You might feel a sudden craving to smoke long after you have given up smoking and stopped**

using NICORETTE® Microtabs. Remember you can use nicotine replacement therapy again if this should happen.

Children aged 12 years and over

Children should follow the guide to stopping immediately. The recommended duration of nicotine replacement therapy in children is 12 weeks maximum. The only time children should stop gradually is if they are having a problem stopping immediately. Talk to your doctor, nurse or pharmacist before attempting to stop gradually.

If you have used too many Microtabs

If you have used more than the recommended number of NICORETTE® Microtabs you may experience nausea (feeling sick), vomiting, increased salivation, pain in your abdomen, diarrhoea, sweating, headache, dizziness, hearing disturbance or weakness.

- If you do get any of these effects contact a doctor or your nearest hospital Accident and Emergency department immediately. Take this leaflet and the pack with you.

If a child has used or swallowed Microtabs

- **Contact a doctor or your nearest hospital Accident and Emergency department immediately** if a child under 12 years uses, chews, sucks or swallows a NICORETTE® Microtab. Take this leaflet and the pack with you.

Nicotine ingestion by a child may result in severe poisoning.

4 Possible side-effects

Like all medicines, NICORETTE® Microtab can have side-effects. As many of the effects are due to nicotine, they can also occur when nicotine is obtained by smoking.

Effects related to stopping smoking (nicotine withdrawal)

You may experience unwanted effects because by stopping smoking you have reduced the amount of nicotine you are taking. You may also experience these effects if you use too few NICORETTE® Microtabs before you are ready to reduce your nicotine intake.

These effects include:

- irritability or aggression
- feeling low
- anxiety
- restlessness
- poor concentration
- increased appetite or weight gain
- urges to smoke (craving)
- night time awakening or sleep disturbance
- lowering of heart rate
- dizziness, lightheadedness, blurry vision, nausea
- cough
- constipation
- bleeding gums
- mouth ulcers
- swelling of the nasal passages and back of the throat

Effects of too much nicotine

You may also get these effects if you are not used to **inhaling tobacco smoke**.

These effects include:

- feeling faint
- feeling sick (nausea)
- headache

Side-effects of nicorette® microtab

if you notice any of the following; fast heart rate/beat, abnormal beating of the heart, chest palpitations, shortness of breath or allergic reactions (swelling of the face, mouth, lips, throat and tongue, itching of the skin, swelling of the skin, ulceration and inflammation of the lining of the mouth, difficulty in breathing and dizziness) stop taking NICORETTE® Microtabs and contact a doctor immediately.

Very common side-effects:

- (may affect more than 1 in 10 people):
- headache
 - throat irritation
 - hiccups
 - feeling sick (nausea)

Common side-effects:

- (may affect up to 1 in 10 people):
- allergic reactions (hypersensitivity)
 - burning sensation in the mouth
 - cough
 - dizziness
 - taste disturbance or loss of taste
 - tingling or numbness of the hands and feet
 - stomach pain or discomfort
 - diarrhoea

- dry mouth
- indigestion
- excessive gas or wind
- increased salivation
- sore and inflamed mouth
- sickness (vomiting)
- tiredness (fatigue)
- nasal irritation
- sore mouth or throat

Uncommon side-effects:

(may affect up to 1 in 100 people):

- abnormal dream
- sudden reddening of the face and/or neck
- high blood pressure
- sudden constriction of the small airways of the lung that can cause wheezing and shortness of breath
- loss or damage to voice
- blocked nose, sneezing
- throat tightness
- burping (belching)
- swollen red sore tongue
- mouth ulcers or blisters
- numbness or tingling of the mouth
- excessive sweating
- itching
- rash
- hives (urticaria)
- unusual weakness
- chest discomfort and pain
- jaw-muscle ache
- general feeling of discomfort or being unwell or out of sorts (malaise)

Rare side-effects:

(may affect up to 1 in 1,000 people):

- difficulty in swallowing
- decreased feeling or sensitivity, especially in the mouth
- feeling of wanting to be sick (vomit)

Other side-effects

- blurred vision, watery eyes
- dry throat, lip pain
- stomach discomfort
- redness of the skin
- muscle tightness

► When you stop smoking you may also develop mouth ulcers. The reason why this happens is unknown.

► If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in this leaflet. You can also report side-effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side-effects you can help provide more information on the safety of this medicine.

5 Storing and disposal

- **Keep NICORETTE® Microtab out of the sight and reach of children and animals.** Nicotine in high doses can be very dangerous and sometimes fatal if taken by children.
- Do not store NICORETTE® Microtab above 25°C.
- Do not use NICORETTE® Microtab after the ‘Use before’ date shown on the

carton or blister.

- Dispose of any unused NICORETTE® Microtab sensibly.
- Medicines should not be disposed of via waste-water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What’s in this medicine?

The active ingredient is: Nicotine. Other ingredients are: β-cyclodextrin, crospovidone, colloidal silica and magnesium stearate.

What the medicine looks like

NICORETTE® Microtab is blister packed in sheets of 10 microtabs, and is available in cartons containing 10, 20, 30, 90, 100, 150 or 210 microtabs. Not all pack sizes may be marketed.

Who makes nicorette® microtab?

The Product Licence holder is McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

The manufacturer is McNeil AB, Helsingborg, Sweden.

This leaflet was revised in January 2019. ©