

NicAssist 2 mg Microtab (Nicotine)

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to help you stop smoking. However, you still need to use it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice
- **Important** these microtabs are sublingual tablets and must be dissolved under the tongue, do not chew or swallow them.

What this medicine is for

This medicine contains nicotine which belongs to a group of medicines called nicotine replacement therapy (NRT). It acts to substitute the nicotine that you normally get from cigarettes and can help you stop smoking.

It can be used to relieve the symptoms of nicotine withdrawal and reduce the cravings for nicotine that you get when you try to stop smoking, or when you are cutting down on the number of cigarettes you smoke while you try to give up.

To help cut down or quit smoking you should also try to use a behavioural support programme to increase your chances of success.

When you stop smoking or cut down the number of cigarettes you smoke, your body misses the nicotine that you have been absorbing from the smoke. You may experience unpleasant feelings and a strong desire to smoke ("craving").

This shows that you were dependent on nicotine. When you use the microtabs, nicotine is released and passes into your body through the lining of your mouth. The nicotine is sufficient to relieve the unpleasant withdrawal symptoms. It will also help to stop your craving to smoke but will not give you the "buzz" you get from 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.

Before you use this medicine

This medicine can be used by adults and children of 12 years and over. However, some people should not use this medicine or should seek the advice of their pharmacist or doctor first.

X Do not use:

- If you are allergic to any of the ingredients in this medicine
- ! Talk to your pharmacist, nurse or doctor:
- If you are in hospital because of heart disease (e.g. heart attack, problems with your heart rate or rhythm, stroke, angina or high blood pressure) try to give up smoking first without using NRT. You can use this medicine to help you stop smoking once you are out of

hospital. For other heart conditions that do not require you to be in hospital, using NRT is better than continuing to smoke

- If you have diabetes monitor your blood sugar levels more often when you start using this medicine. You may find that you need to adjust the amount of insulin you use, or the amount of tablets you take (ask your doctor or diabetes nurse about this)
- If you have an ulcer in your stomach or upper intestine or problems such as pain or swelling of the stomach or oesophagus (the passage between your mouth and stomach)
- If your liver or kidneys do not work properly
- If you have an overactive thyroid gland
- If you have high blood pressure due to a tumour near your kidney (your doctor may have told you that you have a condition called phaeochromocytoma)
- If you are taking other medicines regularly prescribed by your doctor (see "**If you take other medicines**")
- If you have ever experienced seizures (fits)
- If you are pregnant or breastfeeding (see "Other important information")

Other important information

If you are pregnant: You should try to stop smoking without using medicines. If you still need help you can use this product. The risk to your baby whilst using this product is far less than if you continue to smoke. Talk to your pharmacist or doctor for more advice. Products that are used intermittently, such as this one, may be preferable to nicotine patches. However if you feel sick or are sick (morning sickness) the patches may be better for you. If you do use nicotine patches they should be taken off before bedtime.

If you are breastfeeding: You should try to stop smoking without using medicines. If you can't manage this you are best to use an NRT product that is used intermittently (not patches). You should talk to your doctor, nurse or pharmacist for advice.

Breastfeed your baby just before you use the microtab to make sure that your baby gets the smallest amount of nicotine possible.

If you need to use this product, the amount of nicotine that your baby may receive is much smaller and less harmful than the second-hand smoke they would inhale if you smoked. Tobacco smoke causes breathing and other health problems in babies and children. If your husband, partner or other family members smoke too, try to get them to give up with you.

Nicotine products and children: Nicotine can be very dangerous to children. The amount of nicotine tolerated by adults and adolescents can make children very ill, and can sometimes be fatal. Do not leave your microtabs where children may get hold of them.

Information about some of the ingredients in this medicine: This medicine contains 84.65 mg of cyclodextrin(s) in each sublingual tablet.

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

If you take other medicines

Before you use this medicine, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly the following:

 Theophylline, clozapine, ropinirole – your doctor may want to monitor the amount of medicine that you take

When you stop smoking or cut down, your metabolism slows down. This can mean that some medicines may stay in your body longer than usual. If you take any medicine on a regular basis, tell your doctor that you intend to stop smoking and follow his or her advice about these other medicines.

How and when to use this medicine

Check that the foil is not broken before use. If it is do not use that tablet.

How to use the microtab

The tablets must be dissolved slowly under the tongue (about 30 minutes). This will release the nicotine, which you absorb through the lining of your mouth. **Do not** chew or swallow them.

When to use the microtab

Follow the instructions in the table. The table shows you how many microtabs to use, when to use them, how to use them, and the maximum number you should use each day. Read this information carefully and then go to "How to stop smoking – your choice". This section will help you decide which method to use.

The number of microtabs you use each day will depend on how many cigarettes you smoked and how strong they were. See the table below to find out how many microtabs you should use.

If you smoke 20 cigarettes or less per day, you should use one microtab every hour, although you may want to increase to two microtabs every hour if one is not relieving your cravings. If you smoke more than 20 cigarettes per day you should use two microtabs every hour. You must not use more than 40 microtabs a day.

Adults and Children of 12 years and over

| Number of cigarettes you smoke per day | How many and how often to use them | |
|--|------------------------------------|--|
| 20 cigarettes or fewer. | One microtab every hour. | |
| More than 20 cigarettes. | Two microtabs every hour. | |

Most people use between 8 to 24 microtabs per day.

Don't use more than 40 microtabs per day.

Do not use more than the amount recommended.

Children aged 12 to 17 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.

Children under 12 years: Do not give this medicine to children under 12 years of age.

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 the microtabs, you are worried that you will start smoking again without them or you find it difficult to reduce the number of microtabs you are using, talk to your doctor, nurse or pharmacist.

Remember the 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 and 17 years or 18 years and over. Make sure you follow the age range applicable to you.

Adults of 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) | 2 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 the table to decide how many microtabs are 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 microtabs you use each day.** Once you reach only one or two microtabs 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 Boots NicAssist Microtabs. Remember you can use nicotine replacement therapy again if this should happen.

Children of 12 to 17 years

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 that follows.

| Preparation | 8 weeks (2 months) | 4 weeks (1 month) | |
|-------------|-----------------------|----------------------|--|
| 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 the table to decide how many microtabs are 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 microtabs you use each day** over the next 4 week period. Once you reach only one or two microtabs each day you should try to stop completely.

You should make sure that you do this within 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 and 17 years or 18 years and over. Make sure you follow the age range applicable to you.

Adults of 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 | 12 weeks | Gradually |
|-------------|------------|------------|--------------|
| | (6 months) | (3 months) | 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 microtabs every hour to relieve your cravings. See the table to decide how many microtabs are 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 the microtabs. Remember you can use nicotine replacement therapy again if this should happen.

Children of 12 to 17 years

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 use too many microtabs: You may get the following symptoms – nausea (feeling sick), vomiting, increased salivation, pain in your stomach, diarrhoea, sweating, headache, dizziness, hearing disturbance or weakness. If this happens contact a doctor or hospital casualty department straight away. Take the medicine and this leaflet with you.

If an adult accidentally swallows a single microtab it is unlikely to have an adverse effect. You may feel sick or be sick.

If a child under 12 accidentally uses, swallows, sucks or chews some of this medicine take them to casualty immediately. Take the medicine and this leaflet with you. Nicotine ingestion by a child may cause severe poisoning.

Possible side effects

Most people can use this medicine without any problems but sometimes you may notice some side effects. Many of these effects are due to nicotine; they may also happen when you smoke.

If you notice any of the following serious side effects, stop using the medicine, do not smoke and see your doctor as soon as possible.

- You develop a fast, slow or irregular heart beat
- You have an allergic reaction to the microtab such as rash, itching or swelling of the tongue, mouth or throat (go straight to casualty if severe
- You experience seizures (fits)

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
 microtabs before you are ready to reduce your nicotine intake.
 - These effects include:
- Irritability or aggression, feeling low, anxiety, restlessness
- Poor concentration, urges to smoke (craving), night time awakening or sleep disturbance
- Increased appetite or weight gain
- 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 when you smoke. You may be able to relieve these effects by using the microtabs less often.

These effects include:

• Feeling faint, feeling sick (nausea), headache

Side effects of the microtab

Very common side effects:

(more than 1 in every 10 people are affected)

- Headache
- Throat irritation
- Hiccups, feeling sick

Common side effects:

(less than 1 in every 10 people are affected)

- Allergic reactions
- Inflammation of the nose such as a runny, itchy, blocked nose
- Burning sensation in the mouth, dizziness, taste changes, pins and needles
- Cough
- Sore mouth or throat
- Palpitations
- Stomach pain, heartburn, diarrhoea, wind
- Dry mouth, being sick, increase in saliva, inflammation of the mouth
- Feeling tired

Uncommon side effects

(less than 1 in every 100 people are affected)

- · Abnormal dreams
- Changes in heart rhythm (you may notice a fast heart rate or beat)
- Flushing, high blood pressure
- Throat tightness, difficulty breathing, shortness of breath
- Hoarseness of the voice, sneezing, nasal congestion
- Belching, inflammation of the tongue, mouth ulcers, tingling mouth
- Itching, skin rash, hives, excess sweating
- Jaw pain
- Generally feeling unwell or weak, chest pains

Rare side effects:

(less than 1 in every 1,000 people are affected)

- Swelling of the mouth, lips, throat and tongue, swelling and itching of the skin (allergic reaction)
- Difficulty swallowing, retching, mouth feeling numb

Very rare side-effects:

(less than 1 in 10,000 people are affected)

Abnormal beating of the heart

Side effects with unknown frequency:

- Severe allergic reaction, redness of the skin
- Blurred vision, watery eyes
- Dry throat, stomach discomfort, lip pain
- · Tightness of the jaw
- ! When you stop smoking you may also develop mouth ulcers. The reason why this happens is unknown.

Reporting side effects

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.

How to store and dispose of this medicine

Keep this medicine in a safe place out of the sight and reach of children and animals, preferably in a locked cupboard.

Nicotine in high doses can be very dangerous and sometimes fatal if used or swallowed by children.

Use the medicine by the date on the carton and keep it in the original pack.

Do not store above 25°C.

Store it in the original package.

Dispose of any unused microtabs sensibly.

What is in this medicine

This pack contains 100 tablets in blister strips of 10's. Each sublingual tablet contains nicotine 2 mg, which is the active ingredient.

As well as the active ingredient, these tablets also contain ß-cyclodextrin, crospovidone, colloidal silica and magnesium stearate.

Who makes this medicine

This product is manufactured for The Boots Company PLC Nottingham NG2 3AA by McNeil AB Helsingborg Sweden.

The Marketing Authorisation holder is McNeil Products Ltd Maidenhead Berkshire SL6 3UG. Leaflet prepared February 2021

If you would like any further information about this product, please contact The Boots Company PLC Nottingham NG2 3AA.

For more information see our useful tips about giving up smoking.

Other formats

To request a copy of this leaflet in Braille, large print or audio please call, free of charge: **0800 198 5000** (UK only)

Please be ready to give the following information:

Product name: Boots NicAssist 2 mg Microtab

Reference number: 15513/0178

This is a service provided by the Royal National Institute of Blind People

Helpful tips about giving up smoking

You may have tried to stop smoking before and you know from bitter experience that it's not easy to give up cigarettes. However, you have now taken the first constructive step towards becoming a non-smoker. In overcoming your tobacco dependence you will have to tackle two problems:

- 1 Your smoking habit
- 2 Your addiction to nicotine

Willpower

The overriding success factor in quitting is how determined you are. The first few weeks of quitting or reducing the numbers of cigarettes you smoke will probably be the most difficult because your smoking ritual is still fresh in your mind. However, you will find that as time goes by, your willpower becomes stronger.

Telling friends, family and work colleagues that you are stopping smoking and that you envisage a tough time ahead will encourage them to support you.

1 Pick the right day

There is never a perfect time to give up smoking, but you should plan ahead by choosing a date in the not too distant future on which you are going to give up cigarettes completely. Try to pick a day when you will not be too stressed.

2 Break your routine

For a number of years you will have become accustomed to smoking at certain times, with particular people or circumstances. Think about the times you will miss smoking the most and plan how you will cope on these occasions. Changing your routine will help you break the habit of smoking.

3 Quit with a friend

Quitting with a fellow smoker is a good idea. It will strengthen your resolve and build on your determination. Encourage a friend or family member to quit with you. It will give your morale a boost since there will be another person knowing exactly what you're feeling and with whom you can share your determination to quit smoking.

4 Remove any temptation

To help yourself succeed, be sure to remove all cigarettes, matches, lighters etc. from the home, the car, and at work. Ask your friends and colleagues not to offer you cigarettes or smoke close by you – but be careful not to offend them. Explain that you have given up. This type of support from friends is of greatest benefit for the first couple of weeks of quitting, as this is your most vulnerable time. The last thing you want is a cigarette close at hand in a moment of weakness.

5 Take one day at a time

When you reach your Quit Day, don't allow yourself to think that you're quitting for good. That will make it seem like a superhuman task. Just promise yourself "I won't have a cigarette today", and take it one day at a time. You'll be surprised how much that little thought helps.

6 Keep active

Whenever you feel the urge to smoke coming on, distract yourself by keeping active. Don't feel sorry for yourself. Get up and DO something. Do that job around the house or garden that you've been putting off, or take up a hobby. Remember that the craving only lasts a few minutes.

7 Learn to relax

Once you have stopped smoking, taking exercise regularly will not only help you get fitter but will encourage you to relax. Exercise has the ability to relieve stress and tension. Taken regularly it will benefit you physically and psychologically. If you haven't exercised for some time, take it slowly to begin with and increase the amount of time spent exercising over the course of a few weeks. Not only will exercising help you relax but also helps to keep your weight under control, which some people find a problem when quitting.

8 Think cash not ash

One of the really noticeable benefits of "stopping" is the extra cash that's suddenly available. To emphasise the point put the money into a pot marked "cash not ash" and watch it accumulate. But be sure to use the money to treat yourself. You deserve a REWARD for NOT smoking.

9 Dealing with relapses

After you have stopped smoking you might find that in times of stress, reaching for a cigarette is the only thing that will help you through. There may also be certain situations – particularly social situations such as a party – where temptation just gets the better of you, so you smoke one or two cigarettes. You might feel that your only option is to go back to smoking. Don't think of it as having failed, just think through the reasons why you wanted to quit in the first place and don't let those couple of cigarettes get the better of you. Refer back to your plan and start again. You can beat it!

10 If you don't succeed

Giving up is more difficult for some people than others. If you fail to stop first time, don't be disheartened. Try again at a later date – you can do it! Remember the most successful long term ex-smokers have usually had to try several times to stop smoking... if you don't succeed – quit again.

Artwork reference: 625095