

Information for the user



NicAssist 2 mg Lozenge (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
- You must contact a pharmacist or doctor for advice if you need to use the lozenges for longer than 9 months

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 to 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. When you suck the lozenge, nicotine is released slowly and taken into the body through the lining of the mouth.

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

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 known smoking related diseases, not the nicotine.

Before you use this medicine

This medicine can be used by adults of 18 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 (see "What is in this medicine")
- **If you** are a non-smoker
- **If you have phenylketonuria** (this medicine contains aspartame (E951), a source of phenylalanine equivalent to 5 mg per lozenge, which may be harmful to you)
- **If you have an intolerance to some sugars**, unless your doctor tells you to (this medicine contains maltitol, a source of fructose)

! Talk to your pharmacist or doctor:

- If you have heart problems including a previous heart attack, heart failure, problems with your heart rate or rhythm, angina, have had a stroke, or high blood pressure not controlled by medication – try to give up smoking first without using NRT. However, if you still need help to stop smoking you can use this medicine but your doctor may want to monitor you more closely
- If you have high blood pressure
- If you have problems with your circulation
- If you have a tumour near your kidney (your doctor may have told you that you have a

condition called phaeochromocytoma)

- If you have an ulcer in your stomach, or problems such as pain or swelling of the stomach or oesophagus (the passage between your mouth and your stomach)
- If your liver or kidneys do not work properly
- If you have an overactive thyroid gland
- 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 that you use, or the amount of tablets that you take (ask your doctor or diabetes nurse about this)
- If you are on a low salt (sodium) diet (each lozenge contains 9.8 mg sodium, which may be harmful to you)
- If you are pregnant or breastfeeding (see “**Other important information**”)

Other important information

Driving and using machines: Using this medicine is not known to affect your ability to drive or use machines. However you should bear in mind that giving up smoking can change your behaviour.

Using this medicine with food and drink: Coffee, acidic and soft drinks may decrease the absorption of nicotine. Do not drink them for 15 minutes before sucking a lozenge.

Information about some of the ingredients in this medicine: Maltitol (E965) may have a mild laxative effect. Each lozenge contains 0.9 g maltitol. This provides 2 kcal per lozenge. This may need to be taken into account if you have diabetes.

If you are pregnant: You should try to stop smoking without using NRT.

However, if you still need help to stop smoking, you can use this product as the risk to your baby is far less than if you continue to smoke. You should talk to your pharmacist or doctor for more advice.

If you are breastfeeding: You should try to stop smoking without using NRT.

However, if you still need help to stop smoking, you can use this medicine. You should talk to your pharmacist or doctor for more advice.

Do not use the lozenges in the 2 hours before you feed your baby. Then breastfeed your baby just before you use the lozenge, to make sure that your baby gets the smallest amount of nicotine possible.

The amount of nicotine that your baby may receive when you are using the lozenges or other NRT products 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 household 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 lozenges where children may get hold of them.

If you take other medicines

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

- Theophylline (for breathing problems)
- Tacrine (for Alzheimer’s disease)
- Olanzapine or clozapine (used to treat schizophrenia)
- Insulin (for diabetes)

When you stop smoking 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 medicines. This includes medicines prescribed by your doctor and medicine you have bought for yourself, including herbal and homeopathic remedies.

✓ How to use this medicine

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

Read all of the following information carefully before starting to use the lozenges. Ask your pharmacist or doctor if you need any advice.

- To improve your chances of successfully giving up smoking you should stop smoking completely when you start to use the lozenges and when you are using the lozenges
- Use the “How to suck the lozenge” instructions to make sure that you suck the lozenge correctly to release the nicotine

The lozenges are available in two strengths. Use the information and table below to decide which strength of lozenge to use.

- The 2 mg lozenges should be used for strong or very strong nicotine dependent smokers
- You should also use the 2 mg lozenges if you have previously failed to give up smoking using the 1 mg lozenges or if you are worried your cravings for nicotine may make you smoke again

Suck the lozenge. Do not chew or swallow it.

| Low to moderate dependency | Moderate to strong dependency | Strong to very strong dependency |
|-------------------------------|--|----------------------------------|
| | | |
| Less than 20 cigarettes / day | From 20 to 30 cigarettes / day | Over 30 cigarettes / day |
| Use the 1 mg lozenge | Use the 1 mg or 2 mg lozenge depending on how strong your cravings are and your preference | Use the 2 mg lozenge |

If you use the 2 mg lozenge and find that you get side effects, try using the 1 mg lozenge instead.

How to suck the lozenge

1. Suck a lozenge until the taste becomes strong.
2. Rest the lozenge between your gums and cheek.
3. Suck again when the taste has faded.
4. Repeat this routine until the lozenge dissolves completely (about 30 minutes).

How many to use:

Adults over 18 years: Suck one lozenge every one to two hours when you feel the urge to smoke.

Most people use between 8 to 12 lozenges per day. However, if you still have an urge to smoke you can use more lozenges.

Don't use more than fifteen 2 mg lozenges per day.

Normally you should use the lozenges for at least 3 months, but this may vary from person to person. After 3 months, you should gradually reduce the number of lozenges used each day.

When you are using only one or two lozenges per day you should stop completely.

In general you should not use the Boots NicAssist 2 mg Lozenges for more than 6 months. However, some people may need to use them for longer to stop then smoking again.

If you need to use the lozenges for longer than 9 months, ask your pharmacist or doctor for advice.

Counseling may improve your chances of giving up smoking.

Children and adolescents under 18 years: Do **not** use the lozenges, unless your doctor tells you to.

If you use too many: Sucking too many lozenges can result in the same symptoms as smoking too much. The general symptoms of too much nicotine include weakness, sweating, increased production of saliva, throat burn, feeling sick, being sick, diarrhoea, pain in the abdomen, disturbance of hearing and vision, headache, fast, slow or irregular heart beat, shortness of breath and circulatory problems.

If this happens talk to your doctor or pharmacist for advice.

! If a child uses or swallows any lozenges: Talk to a doctor straight away. Take the child to the nearest casualty department. Take the medicine and this leaflet with you. Even small quantities of nicotine are dangerous in children and may result in severe symptoms or death.

Possible side effects

Most people will not have problems, but some may get some of these:

! If you get any of these serious side effects, stop using the lozenges and do not smoke. See a doctor at once:

- Fast, slow or irregular heart beat
- Difficulty breathing, swelling of the lips, face, throat or tongue (signs of severe allergic reaction)

These serious effects are rare, affecting only 1 to 10 people out of 10,000.

If you get any of the following side effects see your pharmacist or doctor:

In the first few days you may feel dizzy, get headaches or have difficulty sleeping. These may be withdrawal symptoms from stopping smoking and may be caused because you are not getting enough nicotine.

Common side effects (affecting 1 to 10 people out of 100)

- Dizziness and headache
- Dryness of the mouth, hiccups, stomach trouble such as feeling sick, flatulence, heartburn, increased saliva production and irritation of the mouth and throat - this may happen because you are sucking the lozenge too fast, try to suck more slowly

Uncommon side effects (affecting 1 to 10 people out of 1000)

- Palpitations

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

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

How to store this medicine

Do not store above 25°C.

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

Use by the date on the end flap of the carton or edge of the blister strip. If you have out of date medicine or you no longer need the lozenges take them to your nearest pharmacy for safe disposal.

What is in this medicine

Each compressed lozenge contains nicotine 2 mg (as nicotine bitartrate dihydrate 6.144 mg), which is the active ingredient.

As well as the active ingredient, the lozenge also contains maltitol (E965), sodium carbonate anhydrous, sodium hydrogen carbonate, polyacrylate, xanthan gum, colloidal anhydrous silica, levomenthol, peppermint oil, aspartame (E951), magnesium stearate.

The pack contains 36, 72, 96, 144 or 204 white, round, mint flavoured lozenges. Not all pack sizes may be marketed.

Who makes this medicine

Manufactured for The Boots Company PLC Nottingham NG2 3AA by GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, UK. Marketing Authorisation held by GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, UK

This leaflet was last revised in April 2016

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

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 Lozenge

Reference number: 44673/0116

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

Component code

Artwork reference: BTC225756