

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **NicAssist 2 mg Lozenge**

#### **Nicotine**

**Read all of this leaflet carefully 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

#### **What is in this leaflet:**

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

#### **1. What NicAssist lozenge is and what it is used 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 quit smoking you should also try to use a behavioural support programme 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.

#### **2. What you need to know before you take NicAssist Lozenge**

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.

#### **Do not use:**

- if you are allergic to any of the ingredients in this medicine (listed in section 6).
- if you have phenylketonia (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)
- if you are a non-smoker

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking this medicine if you:

- have heart disease problems (e.g. a previous heart attack, heart failure, problems with your heart rate or rhythm, angina (chest pain due to reduced blood flow to the heart), including Prinzmetal's angina (chest pain when resting, due to a spasm in the coronary artery)
- have high blood pressure, not controlled by medication
- have had a stroke
- have problems with your circulation
- have a tumour near your kidney (phaeochromocytoma)
- have an ulcer in your stomach, or problems such as pain or swelling of the stomach or oesophagus (the passage between the mouth and your stomach)
- suffer from liver or kidney disease
- have ever experienced seizures
- have an overactive thyroid gland
- 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)
- are on a low-salt (sodium) diet (each lozenge contains 9.8 mg sodium, which may be harmful to you)
- are pregnant or breast-feeding (see Pregnancy/Breast-feeding sections).

### **Children and adolescents (age 12-17 years):**

Do not use the lozenges, unless your doctor tells you to.

**Children under 12 years of age:** Not recommended for use in children under 12 years.

### **Other medicines and NicAssist lozenge**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines particularly the following:

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

When you stop smoking your metabolism slows down. This can mean that some medicine 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 your self, including herbal and homeopathic remedies.

### **NicAssist lozenge with food and drink**

Coffee, acidic and soft drinks may decrease the absorption of nicotine. Do not drink them for 5 minutes before sucking a lozenge.

### **Pregnancy, breast-feeding and fertility**

**Pregnancy:** 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 birth and even stillbirths. It is best if you can give up smoking without the use of medicines containing nicotine. If you cannot manage this, NicAssist lozenge should only be used after consulting a healthcare professional.

**Breast-feeding:** NicAssist lozenge should be avoided during breast-feeding as nicotine is found in breast milk and may affect your child.

If a healthcare professional has recommended you to use NicAssist lozenge during breast-feeding. The lozenge should be sucked just after breast-feeding and not during the two hours before breast-feeding.

### **Fertility**

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

**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. Keep out of the sight and reach of children.

### **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.

**Information about some of the ingredients in this medicine:** This medicine contains 10 mg aspartame in each lozenge. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Because NicAssist Lozenge contains maltitol (E965) a source of fructose:

- if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- patients may experience a mild laxative effect. Calorific value 2.3 kcal/g maltitol. NicAssist lozenge ingredients are suitable for diabetics.

This medicine contains less than 1 mmol sodium (23 mg) per lozenge, that is to say essentially 'sodium free'.

### **3. How to take NicAssist lozenge**

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure. Check the foil is not broken before use. If it is, do not use the lozenge.

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.
- Suck the lozenge. Do not chew or swallow it.
- 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 by smokers smoking more than 30 cigarettes a day.
- 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.

| Low to moderate dependency    | Moderate to strong dependency                                                              | Strong to very strong dependency |
|-------------------------------|--------------------------------------------------------------------------------------------|----------------------------------|
| ← 1 mg lozenge acceptable →   |                                                                                            |                                  |
|                               | ← 2 mg lozenge acceptable →                                                                |                                  |
| 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 one 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.

**Do not use more than 15 mg** of the 2 mg lozenges per day. Do not use more than 1 lozenge per hour.

Normally you should use the lozenges for at least 3 months, but this varies from person to person. After 3 months, you should gradually reduce the number of lozenges used every 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 them smoking again.

If you need to use the lozenges for longer than 9 months, ask your pharmacist or doctor for advice. Counselling may improve your chances of giving up smoking.

**Use in children and adolescents (aged 12-17 years):** Do not use the lozenges, unless your doctor tells you to.

**Use in children below 12 years of age:** Not recommended for use in children under 12 years.

**If you use more lozenges than you should:**

Sucking too many lozenges can result in the same symptoms as smoking too much. The general symptoms of too much nicotine include weakness, excess sweating, pale skin, increased production of saliva, throat burn, feeling sick, being sick, diarrhoea, pain in the abdomen, disturbance of hearing and vision, confusion, tremor, headache, fast, slow or irregular heartbeat, shortness of breath and circulatory problems. If it happens talk to your doctor or pharmacist or nurse.

If you accidentally take too many, or if a child has eaten any, contact your doctor or nearest hospital casualty department immediately, take the pack or leaflet with you if possible.

Nicotine ingestion by a child may result in severe poisoning.

The general symptoms of nicotine overdose include:

- weakness, excess sweating, pale skin, increased production of saliva, throat burn, feeling sick, headache, vomiting, diarrhoea, stomach pains, disturbed hearing and vision, confusion, tremor, disturbance in heartbeat, shortness of breath and circulatory problems

**If you forget to use NicAssist lozenges:**

Do not take a double dose to make up for a forgotten lozenge.

**! If a child uses or swallows any lozenges:**

Talk to a doctor straight away- Take the child to the nearest casualty department. Take the medicines and this leaflet with you. Even small quantities of nicotine are dangerous in children and may result in severe symptoms or death. Keep out of the sight and reach of children.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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

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

**! STOP using the lozenge and seek medical help immediately** if you have any of the following which may be signs of an **allergic reaction**:

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

**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, stomach trouble (such as feeling sick, vomiting, flatulence, pain), increased saliva production, constipation and irritation of the mouth and throat
- indigestion, heartburn or hiccups may happen, because you are sucking the lozenge too fast, try to suck more slowly.

- insomnia
- cough and sore throat

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

- Palpitations

**Not known** (*frequency cannot be estimated from the available data*)

- tremor
- heartbeat irregularities
- breathing difficulty
- difficulty swallowing or belching
- weakness, fatigue or flu-like symptoms
- seizures
- a fast and irregular heartbeat (Atrial fibrillation)

When you stop smoking you may also develop mouth ulcers. Mouth ulcers may be related to quitting smoking and not to your treatment.

### **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](http://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. How to store NicAssist lozenge**

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not use this medicine after the expiry date which is stated on the blister and carton. 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 NicAssist contains**

- The active substance is nicotine bitartrate dihydrate.
- Each compressed lozenge contains nicotine 2 mg (as nicotine bitartrate dihydrate 6.144 mg).
- The other ingredients are: maltitol (E965), sodium carbonate anhydrous, sodium hydrogen carbonate, polyacrylate, xanthan gum, colloidal anhydrous silica, levomenthol, peppermint oil, aspartame (E951), magnesium stearate.

#### **What this medicine looks like and contents of the pack**

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

#### **Marketing Authorisation Holder and Manufacturer**

Manufactured for The Boots Company PLC Nottingham NG2 3AA by

Dr. Reddy's Laboratories (UK) Ltd., 410 Cambridge Science Park, Milton Road, Cambridge, CB4 0PE, UK

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This leaflet was last revised in November 2025.

**Other formats**

To request a copy of the leaflet in braille, large print or audio please, 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: PL 08553/0796

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