

Package leaflet: Information for the user

Benylin Sore Throat Relief Mint Flavour 8mg Compressed Lozenge
Benzocaine

Read all this leaflet carefully before you start taking this medicine because it contains important information for you.

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your doctor or 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 do not feel better or if you feel worse after taking this medicine after 3 days.

What is in this leaflet:

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

1. What this medicine is and what it is used for

This medicine contains benzocaine, a local anaesthetic. It acts by numbing the affected area and thereby relieving the discomfort and irritation of a sore throat.

This medicine is for use in adults and children aged 16 years and over.

2. What you need to know before you take this medicine

Do not take this medicine

- if you are allergic to benzocaine or any of the other ingredients of this medicine (listed in section 6).
- if you are under 16 years of age
- if you have a history of methaemoglobinaemia (a blood disorder)

Warnings and precautions

Stop use and seek immediate medical attention if you or a child in your care develops pale, grey or blue colored skin, lips and nail beds, headache, light headedness, shortness of breath, fatigue, and fast heartbeat. These could be symptoms of Methaemoglobinaemia and require urgent care.

Avoid eating or drinking directly after taking a lozenge.

If you have any known breathing or swallowing problems, , ask your healthcare professional for advice before use. Take additional care when using this medicine and pay close attention to it while it is in

your mouth.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

3. How to take this medicine

Always take 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 recommended dose is:

Adults and children over 16 years of age, Dissolve 1 lozenge slowly in the mouth.

Do not chew or swallow the lozenge. Leave at least two hours between taking each lozenge. Do not take more than 6 lozenges in 24 hours. Use as few lozenges as you are able to in order to relieve your sore throat.

Children aged less than 16 years of age:

Do not use in children less than 16 years of age.

If you take more of this medicine than you should:

Contact your doctor or pharmacist right away if you experience any of these symptoms: shortness of breath and bluish discoloration of the lips and fingers.

If you forgot to take this medicine:

If you forget to take a dose, you can take another lozenge as long as you do not take more than 6 lozenges in any 24-hour period and a minimum of 2 hours has passed since you took the last lozenge. Do not take a double dose.

4. Possible side effects

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

If you experience the following, stop taking this medicine and seek immediate medical help:

Benzocaine may cause abnormal blood pigment levels (methaemoglobinaemia), symptoms of which may include pale, grey or blue coloured skin, lips or nail beds, headache, shortness of breath, increased heart beat, dizziness, confusion, tiredness or lack of energy (these may occur with an unknown frequency)

Other effects which may occur include, although the frequency is not known:

Allergic reaction or skin rashes.

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 HPRA Pharmacovigilance Website: www.hpra.ie.

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

5. How to store this medicine

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 label and carton after EXP.
The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions

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 protect the environment.

6. Contents of the pack and other information

What this medicine contains

The active substance is Benzocaine. Each lozenge contains 8 mg of benzocaine.

The other ingredients are:

Mannitol (E 421), Magnesium Stearate, Xanthan Gum (E 415), Macrogol 6000 (E 1521), Winterfresh Spray dried (containing gum arabic (E414), peppermint, menthol and eucalyptol flavourings), Sucralose (E 955), Acesulfame Potassium (E 950), Hypromellose, Titanium dioxide (E 171), Winterfresh liquid (containing peppermint, menthol and eucalyptol flavourings), Macrogol 400 (E 1521), Polysorbate 80 (E 433), Purified water.

What this medicine looks like and contents of the pack

Oval, white to slightly yellow/beige lozenge with a size of about 14 mm x 9 mm x 6 mm, with debossed arrows on one side and the text “B 8” on the other side.

They are available in a polypropylene container with a flip-open lid.

Pack sizes: Each container contains 20 lozenges.

Marketing Authorisation Holder

Johnsons & Johnson (Ireland) Ltd.
Airton Road
Tallaght
Dublin 24
Ireland

Manufacturer

McNeil AB, Norrbroplatsen 2, Helsingborg, SE-25109, Sweden

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

Ireland: Benylin Sore Throat Relief Mint Flavour 8mg Compressed Lozenge

Finland: Bafumax mint 8 mg imeskelytabletit/komprimerade sugtabletter

Malta: Benylin Sore Throat Rapid Relief 8mg Compressed Lozenges

Sweden: Bafumax mint 8 mg komprimerade sugtabletter

United Kingdom: Benzocaine 8 mg Compressed Lozenges

This leaflet was last revised in Feb-2022