

MEROCAINE LOZENGES

Benzocaine 10mg and Cetylpyridinium chloride 1.4mg

Read all of this leaflet carefully before you starting taking Merocaine lozenges because it contains important information for you.

Always take Merocaine lozenges exactly as described in this leaflet or as your 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 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 three days.

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1. What Merocaine Lozenges are and what they are used for

These lozenges contain benzocaine and cetylpyridinium chloride and are for the temporary relief of pain and discomfort in sore throats and superficial mouth infections. It is also used for symptomatic relief of pain and discomfort in more serious throat infections such as tonsillitis and pharyngitis.

2. What you need to know before you take Merocaine Lozenges

Do not take Merocaine Lozenges

- If you are allergic to any of the ingredients in this product listed in section 6. See 'Contents of the pack and other information' for the full list of ingredients
- If you have been told by your doctor that you have an intolerance to some sugars. The product contains 1.37g sucrose per dose and 1.0496g glucose per dose. This should be taken into account in patients with diabetes mellitus.

Warnings and Precautions

Use of this product may cause methaemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in the blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- Pale, grey, or blue coloured skin (cyanosis)
- Severe headache
- Rapid heart rate
- Shortness of breath
- Dizziness or lightheadedness
- Fatigue or lack of energy

Pregnancy and breastfeeding

- 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.

Important information about some of the ingredients of Merocaine Lozenges

Merocaine Lozenges contains sucrose and glucose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

3 How to take Merocaine Lozenges

Adults and children 12 years and over:

- Allow a lozenge to dissolve slowly in the mouth.
- One lozenge every 2 hours as needed.
- Do not take more than 8 lozenges in 24 hours.

Children under 12 years:

- Do not use in children under 12 years of age.

If you take more Merocaine Lozenges than you should

If you take more of the lozenges than you should, speak to your doctor or pharmacist.

4. Possible side effects

As with all medicines, Merocaine Lozenges can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

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

- A blood condition called methaemoglobinaemia which can cause headache, breathlessness and blue-tinged skin, may occur rarely. If you suffer this serious side effect, stop taking the lozenges and call your doctor or local hospital immediately.
- Allergic reactions have been reported. If symptoms persist or are severe, or are accompanied by fever, headache, nausea, vomiting tell your doctor.
- Hypersensitivity, sensitisation, urticaria (hives)
- Oral discomfort

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, Earlsfort Terrace, IRL - Dublin 2.

Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie;

email: medsafety@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 out of the reach and sight of children.
- Do not store above 25°C.
- Do not use Merocaine lozenges after the expiry date which is stated on the blister foil after 'EXP'. The expiry date refers to the last day of that month.

- If you find that you still have this medicine after its expiry date, return it to your local pharmacist who will dispose of it properly.

6. Contents of the pack and other information

What Merocaine lozenges contain

Each lozenge contains 10mg of the active ingredient benzocaine and 1.4mg of the active ingredient cetylpyridinium chloride.

Cetylpyridinium chloride has antibacterial properties and benzocaine acts as a local anaesthetic for the symptomatic relief of throat irritations.

They also contain lime oil, lemon oil, sucrose granular, glucose liquid 80%, quinolone yellow (E104) and indigo carmine (E132).

What Merocaine lozenges look like and contents of the pack

Each pack contains 24 clear green, circular, lemon-lime flavor lozenges.

Marketing Authorisation Holder:

Sanofi-aventis Ireland Ltd., T/A SANOFI
Citywest Business Campus
Dublin 24.

Manufacturer:

SSL International plc
Whitehouse Business Park, Traynor Way, Peterlee, County Durham, SR8 2RU,

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