

Dorithricin[®]

Throat lozenges Classic



Package leaflet: Information for the user

Dorithricin[®] throat lozenges Classic 0.5 mg / 1.0 mg / 1.5 mg, lozenges

Active substances: tyrothricin / benzalkonium chloride / benzocaine

Read all of 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 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. 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 2 days.

What is in this leaflet

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2. What you need to know before you take Dorithricin[®] throat lozenges Classic
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1. What Dorithricin[®] throat lozenges Classic are and what they are used for

Dorithricin[®] throat lozenges Classic are a mouth and throat medicine.

Therapeutic indication

For the symptomatic treatment of infections of the mouth and throat associated with sore throat and difficulty swallowing.

2. What you need to know before you take Dorithricin[®] throat lozenges Classic

Do not take Dorithricin[®] throat lozenges Classic

- if you are allergic to tyrothricin, benzalkonium chloride, benzocaine or any of the other ingredients of Dorithricin[®] throat lozenges Classic (listed in section 6).

Warnings and precautions

You should ask a doctor for advice if you have a severely inflamed or sore throat accompanied by high fever, headache, nausea or vomiting.

Your doctor will decide whether you can take Dorithricin[®] throat lozenges Classic in addition to other treatments such as antibiotics, especially if you have purulent tonsillitis with fever.

You should not use Dorithricin[®] throat lozenges Classic if you have any open wounds in the mouth or throat.

Patients with a tendency for hypersensitivity reactions of the skin (allergic contact dermatitis) should avoid taking Dorithricin[®] throat lozenges Classic because of the risk of hypersensitivity reactions.

Children

Dorithricin[®] throat lozenges Classic are not suitable for infants and toddlers under 24 months of age because infants and toddlers cannot be relied upon to take (suck) this medicine properly.

When giving this medicine to children, care should be taken to ensure that they are already able to suck lozenges in a controlled manner.

Other medicines and Dorithricin[®] throat lozenges Classic

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

To date, there have been no reports of any interactions with other medicines when used as directed.

Pregnancy and breast-feeding

To date, there has been no evidence of any harmful effects of Dorithricin[®] throat lozenges Classic on a developing baby. Still, as a safety precaution, you should use this medicine during pregnancy and whilst breast-feeding only after consulting your doctor or pharmacist.

Dorithricin[®] throat lozenges Classic contain sorbitol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Dorithricin[®] throat lozenges Classic.

Patients with rare hereditary problems of fructose intolerance should not take Dorithricin[®] throat lozenges Classic.

Information for diabetics

Each lozenge contains 0.87 g sorbitol (a source of 0.22 g fructose) equivalent to approximately 0.07 carbohydrate exchanges. Sorbitol can have a mild laxative effect.

3. How to take Dorithricin[®] throat lozenges Classic

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

Allow 1-2 lozenges to dissolve slowly in your mouth several times a day, at intervals of 2-3 hours, as required.

Treatment should be continued for another day beyond resolution of symptoms.

If you take more Dorithricin[®] throat lozenges Classic than you should

When used as directed, poisoning with Dorithricin[®] throat lozenges Classic can be excluded and has not yet been reported.

After ingesting a very large number of tablets, patients may experience gastrointestinal symptoms and children in particular may develop an elevated concentration of methaemoglobin in the blood. Possible signs include shortness of breath and bluish discolouration of the lips and fingers.

If you suspect a substantial overdose, be sure to contact a doctor.

Recommended actions to take include the administration of large amounts of water and activated charcoal tablets and, if necessary, appropriate medical interventions to reverse methaemoglobinaemia.

If you forget to take Dorithricin[®] throat lozenges Classic

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

Suck 1 Dorithricin[®] throat lozenge Classic immediately and then continue your usual dosing schedule.

4. Possible side effects

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

The assessment of side effects is based on the following frequency categories:

- Very common: more than 1 in 10 patients treated with this medicine
- Common: 1 to 10 in 100 patients treated with this medicine
- Uncommon: 1 to 10 in 1,000 patients treated with this medicine
- Rare: 1 to 10 in 10,000 patients treated with this medicine
- Very rare: less than 1 in 10,000 patients treated with this medicine
- Not known: cannot be estimated from the available data

Possible side effects

Rare:

Patients may rarely experience hypersensitivity reactions, especially to a metabolite of benzocaine (aminobenzoic acid ester).

When benzocaine has been used externally, an elevated concentration of methaemoglobin in the blood has occurred, especially in children and when applied to larger wound areas. Possible signs include shortness of breath and bluish discolouration of the lips and fingers.

Frequency not known:

In sensitive patients, allergic reactions may also be caused by substances that are chemically related to benzocaine, such as penicillins, sulphonamides, sunscreen cosmetic products, p-aminosalicylic acid (para group sensitisation).

Other possible side effects

Mint oil may trigger hypersensitivity reactions (including shortness of breath) in sensitised patients.

Reporting of side effects



If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

for Germany:

Bundesinstitut für Arzneimittel und Medizinprodukte [Federal Institute for Drugs and Medical Devices]
Abt. Pharmakovigilanz [Drug Safety Unit]
Kurt-Georg-Kiesinger Allee 3
D-53175 Bonn
Website: <http://www.bfarm.de>

for Luxembourg:

Direction de la Santé [Department of Health] – Division de la Pharmacie et des Médicaments [Division of Pharmacy and Medicines]
Villa Louvigny – Allée Marconi
L-2120 Luxembourg
Website: <http://www.ms.public.lu/fr/activites/pharmacie-medicament/index.html>

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

5. How to store Dorithricin® throat lozenges Classic

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 carton and container after "Verwendbar bis:". The expiry date refers to the last day of that month.

Storage conditions

Do not store above 25°C.

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 Dorithricin® throat lozenges Classic contain

- The active substances are:
Each lozenge contains:

| | |
|-----------------------|--------|
| tyrothricin | 0.5 mg |
| benzalkonium chloride | 1.0 mg |
| benzocaine | 1.5 mg |
- The other ingredients are:
sorbitol (Ph. Eur.), talcum, sucrose stearate type III, saccharin sodium 2 H₂O, mint oil, povidone (K25),
carmellose sodium (Ph. Eur.)

What Dorithricin® throat lozenges Classic look like and contents of the pack

White, round tablets

Packs of 20 lozenges and 40 lozenges

Marketing Authorisation Holder

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Unofficial translation of the German package leaflet.

