

Dorithricin® THROAT LOZENGES

Important information, read carefully!

Composition _____ (per lozenge)

Tyrothricin _____ 0,50 mg

Benzalkonium chloride _____ 1,00 mg

Benzocaine _____ 1,50 mg

The other ingredients are:

Sorbitol (Ph. Eur.), talc, sucrose stearate type III, saccharin-sodium 2H₂O, mint oil, providone (K 25), carmellose sodium

For diabetic patients: 1 lozenge contains 870,7 mg sorbitol

Properties

Dorithricin® Throat Lozenges are highly effective in the treatment of painful inflammations of the oral cavity and pharynx. They are fast painkillers due to the proven surface anaesthetic Benzocaine. Their high antimicrobial effect inhibits infection. The efficacy of the specific topical antibiotic Tyrothricin, which is germ-hindering and germicidal and Benzalkonium chloride, which is antiseptic highly effective are both directed at the most frequently occurring germs which produce painful inflammations in the oral cavity and pharynx.

By combining the two antimicrobial active substances, the main pathogens are also overcome.

Dorithricin® Throat Lozenges are well-tolerated, conducive to mucosa regeneration, and speed up the healing process.

Indications

Sore throat, stomatitis (inflammation of the mouth), pharyngitis (inflammation of the pharynx), laryngitis (inflammation of the larynx), gingivitis (inflammation of the gums).

Contraindications

None known. Generally well-tolerated.

Incompatibilities

None known.

Drug Interactions

Patients that are administered local anaesthetics may be at increased risk of developing methaemoglobinaemia when concurrently exposed to the following oxidizing agents:

- Nitrates/Nitrites (eg. nitroglycerin, nitroprusside, nitric oxide, nitrous oxide)
- Local anaesthetics (eg. lidocaine, bupivacaine, mepivacaine, tetracaine, prilocaine, procaine, articaine)
- Antineoplastic agents (eg. cyclophosphamide, flutamide, rasburicase, isofamide, hydroxyurea)
- Antibiotics (eg. dapsone, sulphonamides, nitrofurantoin, para-aminosalicylic acid)
- Antimalarials (eg. chloroquine, primaquine)
- Anticonvulsants (eg. phenytoin, sodium valproate, phenobarbital)
- Other drugs (eg. acetaminophen, metoclopramide, sulfa drugs [i.e. sulfasalazine], quinine)

Doses and administration

Unless otherwise prescribed by your physician, allow 1-2 lozenges to dissolve slowly in the mouth several times daily. The treatment should be continued for one day after the complaints have subsided.

Warnings and Precautions

When sore throat is accompanied by fever, ask your physician promptly if antibiotics should be taken additionally.

You should not take Dorithricin® Throat Lozenges if you have fresh wounds in the mouth or throat.

Methaemoglobinaemia

Cases of methaemoglobinaemia have been reported in association with local anaesthetic use, but only few cases were associated with the application of benzocaine-containing lozenges. Although all patients are at risk for methaemoglobinaemia, patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methaemoglobinaemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition. If local anaesthetics must be used in these patients, close monitoring for symptoms and signs of methaemoglobinaemia is recommended.

Signs and symptoms of methaemoglobinaemia can occur immediately after exposure or develop after some hours. The most significant symptoms are a cyanotic skin discoloration and abnormal colouration of the blood. Other signs like dyspnoea, dizziness and somnolence might also indicate methaemoglobinaemia. Methaemoglobin levels may continue to rise; therefore, immediate treatment is required to avert more serious central nervous system and cardiovascular adverse effects, including seizures, coma, arrhythmias, and death. Discontinue Dorithricin® and any other oxidizing agents (see section Drug Interactions) and contact your doctor immediately.

Side effects, accompaniments

Hypersensitivity reactions can be caused by application of Benzocaine.

Cases of methaemoglobinaemia (an elevated level of methaemoglobin in the blood) have occurred after topical application, particularly in children or when applied to fairly large wounds.

Overdose

Poisoning with Dorithricin® Throat Lozenges can be ruled out if used correctly.

Gastrointestinal symptoms and increased methaemoglobin formation (particularly in children) can occur after the administration of large numbers of lozenges. Please contact a doctor if a substantial overdose is suspected – particularly in children.

Package sizes

Packages containing 20 lozenges (packages for hospital)

Store at or below 25°C.**Keep out of reach of children!**

It is not known whether Dorithricin® can cause fetal harm when administered during pregnancy. Dorithricin® should be given during pregnancy only if clearly needed.

Marketed by:
(Hyphens)

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