1. NAME OF THE MEDICINAL PRODUCT

Trachitol® lozenges 1 mg + 1.8 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Trachitol® lozenge contains 1.0 mg of Lidocaine hydrochloride (as monohydrate) and 1.8 mg of Propyl-4-hydroxybenzoate.

Excipient: Each lozenge contains 0.69 g Sorbitol

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lozenge
White, round, flat lozenge with bevelled edge.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Inflammatory diseases of the oral and pharyngeal cavities: Inflammation of the oral mucosa and the gums, tonsillitis, laryngitis, sore throat and infections of the upper respiratory tract.

4.2 Posology and method of administration

Route of administration: Oropharyngeal

Let dissolve one lozenge every 2 hours slowly in the mouth.

The maximum daily dose of 8 lozenges (adults) respectively 6 lozenges (children) should not be exceeded.

Not suitable for very small children, who are not able to suck a lozenge.
If there is no significant improvement after 7 (3-10) days, a physician should be consulted.

4.3 Contraindications

Hypersensitivity to lidocaine hydrochloride and propyl-4-hydroxybenzoate or to any of the excipients.

4.4 Special warnings and precautions for use

Trachitol® contains 0.69 mg sorbitol, corresponding to 0.057 BU. Patients with rare hereditary problems of fructose intolerance should not take this medicine after consultation with the doctor.
Trachitol Lozenges contain Lidocaine. Cross-allergy to lidocaine hydrochloride is expected in patients with a history of known allergy to other local amide type anaesthetics

4.5 Interaction with other medicinal products and other forms of interaction

Adverse effects associated with the concomitant use of other drugs in conjunction with Trachitol® Lozenges have not become known so far.

4.6 Pregnancy and lactation

Trachitol should only be used during pregnancy or lactation after consulting a doctor.

4.7 Effects on ability to drive and use machines

If Trachitol is used according to the instructions no consequences are to be expected.

4.8 Undesirable effects

Very common: ≥1/10
Common: ≥1/100 to <1/10
Uncommon: ≥1/1000 to <1/100
Rare: ≥1/10 000 to <1/1000
Very rare: <1/10 000
Not known: cannot be estimated from available data

In very rare cases hypersensitivity reactions such as local irritation, oropharyngeal swelling, skin reactions or shortness of breath may occur. Severe or generalized courses cannot be excluded.
The product may lead to gustatory disturbances and oral hypoesthesia, like numbness of the tongue,
which disappear spontaneously after withdrawal of the product.

4.9 Overdose

Even if applied a whole package of Trachitol® Lozenges at once, no systemic adverse effects of the active ingredients are expected due to their low content.
Gastrointestinal disorders may occur due to the sorbitol content.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anaesthetic, local
ATC code: R02AD
Lidocaine hydrochloride is a local anaesthetic of the amide type.
Propyl-4-hydroxybenzoate is a preservative. This surface-active agent denatures proteins through esters of para-hydroxy benzoic acid

5.2 Pharmacokinetic properties

Lidocaine hydrochloride
Is indeed absorbed after administration but is 50% inactivated after the first pass through the liver. The amount of active ingredient of 1.0 mg contained in Trachitol® Lozenges practically excludes a systemic effect.

Propyl-4-hydroxybenzoate
Is quickly absorbed and is hydrolysed in the liver and kidneys. Cumulation does not occur.

5.3 Preclinical safety data

No special precautions. No particulars.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Alum
Peppermint oil
Sorbitol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months

6.4 Special precautions for storage

Store below 25°C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Pack size: 20 lozenges. Each AL / PVC blister contains 10 lozenges.
Pack size: 30 lozenges. Each AL / PVC blister contains 15 lozenges.
The blisters are packed in carton boxes.

6.6 Special precautions for disposal and other handling

No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Engelhard Arzneimittel GmbH & Co.KG
Herzbergstr. 3
61138 Niederdorfelden, Germany

8. MARKETING AUTHORISATION NUMBER(S)

MA048/00202

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28th August 2006

10. DATE OF REVISION OF THE TEXT

February 2018