

TRACHISAN®

Forte Lozenges

Package leaflet: Information for the user

Trachisan® Forte Lozenges

Active substance: Lidocaine hydrochloride 1 H₂O.

Please read all of this leaflet carefully, as it contains important information for you. This medicine is also available without a prescription from the doctor. In order to achieve the best results from Trachisan® Forte Lozenges, the lozenges must, however, be taken correctly.

- Please keep this leaflet somewhere safe. You may want to read it again.
- If you need more information or have any questions, ask your doctor or pharmacist.
- If your symptoms get worse or do not improve after 3 days, you must go and see your doctor.
- If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

This leaflet contains the following information:

1. What Trachisan® Forte Lozenges are and what they are used for
2. Before you use Trachisan® Forte Lozenges
3. How to use Trachisan® Forte Lozenges
4. Possible side effects
5. How to store Trachisan® Forte Lozenges
6. Further information

1. WHAT TRACHISAN® FORTE LOZENGES ARE AND WHAT THEY ARE USED FOR

These lozenges belong to the group of medicines called sore throat remedies (local anaesthetics)

Trachisan® Forte Lozenges are used for the short-term local treatment of sore throat in non-purulent infections.

2. BEFORE YOU USE TRACHISAN® FORTE LOZENGES

Trachisan® Forte Lozenges may not be used if you are hypersensitive (allergic) to lidocaine hydrochloride or other amide type local anaesthetics, or any of the other ingredients contained in the product.

Children under the age of 12 may not use Trachisan® Forte Lozenges (also see next section).

Particular care is needed in the following cases when using Trachisan® Forte Lozenges

- Severe sore throat accompanied by a high temperature, headache, nausea or vomiting. In order to avoid complications, Trachisan® Forte Lozenges may not be used for longer than 2 days without medical advice.
- Local anaesthetics can affect swallowing and increase the risk of choking, particularly among younger children (see section

Trachisan® Forte Lozenges may not be used). Eating or drinking immediately after having taken the lozenges should therefore be avoided. The numbness of the tongue and oral mucosa caused by the lozenges can increase the risk of bites. Repeated use can numb the throat and lead to difficulty in swallowing as a result.

- The active ingredient may be absorbed to a greater extent in patients with severe injuries and/or inflammation in the oral and pharyngeal mucosa. This applies particularly to patients suffering from cardiovascular disorders or those with a tendency to suffer from cramp.
- Known allergy to other local anaesthetics of the amide type, as crossallergy to lidocaine hydrochloride 1H₂O, the active ingredient in Trachisan® Forte Lozenges, can be expected.
- Patients with impaired liver and/or kidney function, as these conditions can lead to an increased level of the active ingredient in the blood.

Children and adolescents

Children below the age of 12 may not use Trachisan® Forte Lozenges (see section Trachisan® Forte Lozenges may not be used). Insufficient information is available on the effectiveness and safety of Trachisan® Forte Lozenges in children and adolescents between the age of 12 and 17.

Using Trachisan® Forte Lozenges with other medicines

The following interactions associated with lidocaine have been reported. They are not, however, expected to occur if Trachisan® Forte Lozenges are used correctly.

- Cimetidine (an active ingredient used for treating excessive gastric acid) and beta-blockers, particularly propranolol (specific agents for high blood pressure) can lead to a rise in the concentration of lidocaine in the blood.
- Benzodiazepines (specific sedatives) and barbiturates (specific sleep-inducing medicines) can result in a drop in the concentration of lidocaine in the blood.

Please tell your doctor or pharmacist if you are taking / using or have recently taken / used other medicines, even non-prescription medicines.

Pregnancy

Trachisan® Forte Lozenges may be used during pregnancy only if considered absolutely necessary and only after consulting your doctor. Before you take any medicine, please ask your doctor or pharmacist for advice.

Breast-feeding

If used correctly, Trachisan® Forte Lozenges will cause no harm during breast-feeding. Please however ask your doctor or pharmacist before you start using them.

The ability to drive and operate machines

If used correctly, no effects on driving are to be expected.

Important warnings on certain other ingredients contained in Trachisan® Forte Lozenges:
This medicine contains sorbitol.
1 lozenge contains 0.66 g sorbitol, equivalent to 0.055 BU. If you know you suffer from glucose intolerance, do not take Trachisan® Forte Lozenges until you have spoken to your doctor. Sorbitol can cause gastro-intestinal complaints and diarrhea.

3. HOW TO USE TRACHISAN® FORTE LOZEN-
GES

Always take Trachisan® Forte Lozenges exactly as described in this leaflet. If you are unsure about anything, please ask your doctor or pharmacist.

Unless otherwise prescribed by your doctor, the usual dose is:
Adults take 1 lozenge every 2 hours. The maximum daily dose of 6 lozenges may not be exceeded.

How do I use Trachisan® Forte Lozenges?
For use in the oral and pharyngeal cavities (allowing the lozenge to melt slowly in the mouth).

How long should I use Trachisan® Forte Lozenges?
Do not use Trachisan® Forte Lozenges for longer than 3 days without medical advice.

If you think that the effects of Trachisan® Forte Lozenges® are too strong or too weak, please talk to your doctor or pharmacist.

What should I do if I took too many Trachisan® Forte Lozenges:
Contact your doctor or pharmacist immediately.
Taking too many Trachisan® Forte Lozenges may result in lidocaine over-dosage. This can cause symptoms such as restlessness, dizziness, nausea, impaired hearing and vision as well as impaired co-ordination. Severe lidocaine over-dosage can lead to cramp attacks, unconsciousness or respiratory and cardiovascular failure.

What if I forget to take Trachisan® Forte Lozenges:
Do not double-up on a dose to make up for the one you have missed. Continue treatment as described above (let one lozenge melt in the mouth every 2 hours) (maximum daily dose: 6 lozenges).

What effects are possible if I stop using Trachisan® Forte Lozenges:
None known to date.

4. POSSIBLE SIDE EFFECTS

As with all medicines, Trachisan® Forte Lozenges can have side effects although not everybody gets them.

The incidence and classification of side effects is based on the following figures:

Very common: More than 1 in 10 patients treated

Common: 1 to 10 in 100 patients treated
Uncommon: 1 to 10 in 1,000 patients treated
Rare: 1 to 10 in 10,000 patients treated
Very rare: Less than 1 in 10,000 patients treated
Unknown: Frequency on the basis of available data not assessable


Possible side effects

Diseases of the immune system
Very rare:
Hypersensitivity reactions or sensitisation in the oral region.

Diseases of the gastro-intestinal tract
Rare:
As a result of the desired pain-relieving effect, taste may be affected or the tongue may feel numb. These effects usually disappear quickly.
Very rare:
Owing to the sorbitol contained therein, the lozenges may have a laxative effect.

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TRACHISAN® FORTE LO-
ZENGES

 **Keep all medicines out of the reach and sight of children.**

Do not use this medicine after the date printed on the container (blister) and box. The expiry date refers to the last day of that month.
Do not store above 25° C.

6. FURTHER INFORMATION

What Trachisan® Forte Lozenges contain
The active substance is lidocaine hydrochloride 1H₂O. 1 lozenge contains 8 mg lidocaine hydrochloride 1H₂O.
The other ingredients are: sorbitol (Ph. Eur.), magnesium stearate (Ph. Eur.) [vegetable], anhydrous citric acid (Ph. Eur.), acesulfame potassium, citron flavour, lemon juice flavour.

What Trachisan® Forte Lozenges look like and contents of the pack
Trachisan® Forte Lozenges are available in packs of 20 lozenges.

Marketing authorisation holder and manufacturer
Engelhard Arzneimittel GmbH & Co. KG
Herzbergstrasse 3, 61138 Niederdorfelden
Germany

Date of information: January 2019



Revised: 04/19; PB1715101