

Faringobloc 5 mg /1.5 mg compressed lozenges

Chlorhexidine dihydrochloride/Benzocaine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or nurse have 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, pharmacist or nurse. 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 5 days.

What is in this leaflet:

1. What Faringobloc is and what it is used for
2. What you need to know before you use Faringobloc
3. How to use Faringobloc
4. Possible side effects
5. How to store Faringobloc
6. Contents of the pack and other information

1. What Faringobloc is and what it is used for

Faringobloc compressed lozenges is intended for local application in order to reduce microbial count in inflammatory diseases of the oral cavity (stomatitis, gingivitis, aphthae) and the throat (tonsillitis, pharyngitis, laryngitis).

2. What you need to know before you use Faringobloc

Do not use Faringobloc:

- If you are allergic to chlorhexidine, benzocaine or any of the other ingredients of this medicine (listed in section 6);
- If you have wounds or ulcerations in the mouth or throat;
- If you have been told that you have low plasma levels of the enzyme cholinesterase;
- In children aged less than 4 years.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Faringobloc.

You should know that:

Faringobloc compressed lozenges should be used with caution and under medical supervision if you have sores and ulcerations in the oral and throat mucosa.

The long term (more than one week) use of chlorhexidine-containing medicinal products may lead to reversible staining of the tongue and teeth.

Children and adolescents

This medicine is not intended for use in children aged less than 4 years.

Other medicines and Faringobloc

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

Tell your doctor or pharmacist if you are taking or have recently taken any medicines of the sulfonamide or aminosalicylate group. Benzocaine decreases the effect of these medicines.

Faringobloc with food, drink and alcohol

Do not eat or drink for 30 minutes after taking this medicine.

Pregnancy, breast-feeding and fertility

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.

So far no contraindications have been known for the use of this medicinal product during pregnancy and breast-feeding.

Driving and using machines

No data exist of any influence on the ability to drive and use machines.

Faringobloc contains the excipient aspartame

Due to the contents of aspartame, this product should not be used in people with phenylketonuria (an inherited metabolism disorder that causes an amino acid called phenylalanine to build up in the body).

3. How to use Faringobloc

Always use this medicine exactly as described in this leaflet or your doctor, pharmacist or nurse has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and children aged 12 and over:

1 lozenge several times/day. In case of need, one lozenge every 1-2 hours until the maximum dose of 8 lozenges/day is reached.

Use in children and adolescents

Children aged 4 to 12 years:

Up to 4 lozenges, to take every few hours.

Children aged less than 4 years:

It should not be used in this age group.

The treatment should be initiated with the appearance of the first symptoms, and continue for 1-2 days after symptoms resolve.

Method of administration:

For oromucosal administration.

Lozenges should be kept in the mouth until dissolved. Do not swallow them!

It is advisable not to eat or drink for 30 minutes after taking a lozenge. Take the last lozenge before going to bed and at least 30 minutes after brushing your teeth.

If you take more Faringobloc than you should

If the product is used according to recommendations, the probability of overdosing is minimum.

Signs of overdose may occur only in case of ingestion of a great amount of the medicine.

In such case you should talk to the doctor for advice.

If you forget to take Faringobloc

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

If you missed taking a dose, do it at the time of the next regular administration.

If you have any further questions on the use of this medicine, ask your doctor, or pharmacist, or nurse.

4. Possible side effects

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

The long term use may lead to a transient taste alteration, and a burning and stiff tongue sensation.

Long term (more than one week) use of chlorhexidine-containing medicinal products may result in teeth staining that may be cleaned by using toothpaste. Reversible tongue staining is also possible.

Cases of local irritant effect and contact allergy are rarely observed.

In very rare cases, general hypersensitive reactions to anaphylactic shock (life-threatening allergic reaction) are also possible.

Benzocaine use is related to blood disorders in young children (methemoglobinemia – pathologic hemoglobin formation).

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

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

5. How to store Faringobloc

Keep this medicine out of the sight and reach of children.

Store below 25°C.

Do not use this medicine after the expiry date which is stated on the carton after Exp.: The expiry date refers to the last day of that month.

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 Faringobloc contains

The active substances in 1 lozenge are: chlorhexidine dihydrochloride 5 mg and benzocaine 1.5 mg.

The other ingredients (excipients) are: isomalt, macrogol 6000; mint flavour (menthol, mentone, peppermint essential oil, maltodextrin, sodium starch octenyl succinate E 1450); aspartame (E 951); magnesium stearate.

What Faringobloc looks like and contents of the pack

White or almost white, round, flat, scored on one side compressed lozenges with mint flavour.

The package contains 10 lozenges in PVC/AL blister foil.

2 blisters x 10 lozenges with a package leaflet in a folding carton box.

Marketing Authorisation Holder and Manufacturer

Adipharm EAD

130, Simeonovsko shosse Blvd.

1700 Sofia

Bulgaria

This leaflet was last revised in: January 2020