

## Package leaflet: Information for the user

### Faringodol forte 150 mg lozenges choline salicylate

**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 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, ask your doctor or pharmacist for advice. 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 1–2 days.

#### What is in this leaflet

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

#### 1. What Faringodol forte is and what it is used for

Faringodol forte lozenges contain choline salicylate, a salicylic acid derivative. Salicylates have an anti-inflammatory, as well as an analgesic effect. The administration of choline increases the excretion of saliva that adds to the anti-inflammatory effect of the preparation.

Choline salicylate has a mild bactericidal effect.

Faringodol forte lozenges are suited for the symptomatic treatment of the inflammation of the pharynx, mouth mucous membranes, gums and the periodontal ligament.

#### 2. What you need to know before you use Faringodol forte

##### Do not use Faringodol forte lozenges

- if you are allergic to salicylates, other non-steroidal anti-inflammatory drugs or any of the other ingredients of this medicine (listed in section 6);
- in case of oesophageal varices (risk of bleeding);
- if you have phenylketonuria;
- if your younger than 12-year-old child has been prescribed medicines containing acetylsalicylic acid.

##### Warnings and precautions

- if you are pregnant;
- in case of inflammatory gastrointestinal diseases, peptic ulcer disease or bronchial asthma;
- if your child is under 12 years of age;

Talk to your doctor or pharmacist before using Faringodol forte.

##### Other medicines and Faringodol forte

Salicylates can reduce the activity of concomitantly administered non-steroidal anti-inflammatory drugs and increase the activity of tranquillisers, hypnotics, blood sugar reducing medicines and anticoagulants.

When used concomitantly with salicylates, both steroidal and non-steroidal anti-inflammatory drugs, as well as anticoagulants can increase the risk of gastric bleeding.

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

### **Pregnancy and breast-feeding**

Only use during pregnancy and breast-feeding under the doctor's recommendation. 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.

### **Faringodol forte contains isomalt, maltitol solution and aspartame**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains 1.75 mg aspartame per lozenge. Aspartame is a source of phenylalanine. This can be harmful if you have phenylketonuria, a rare genetic disorder in which phenylalanine is not broken down and builds up in the body.

## **3. How to use Faringodol forte**

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

*Adults and children over 12 years of age:* the regular dose is one lozenge 4–6 times per day.

*Children aged 6–12 years:* the maximum dose is 4 lozenges per day.

If your throat pain does not recede in 1–2 days, talk to your doctor.

### **If you take more Faringodol forte than you should**

Due to the form of the medicine (lozenges) and minimum absorption, the risk of an overdose is very unlikely.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. In rare cases, oral salicylates can cause allergic reactions (redness of the skin or rash, cough, nasal congestion, facial swelling, laboured swallowing and breathing) or gastrointestinal mucous membrane damage (stomach pain, vomiting, gastrointestinal bleeding).

### **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 [www.ravimiamet.ee](http://www.ravimiamet.ee). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Faringodol forte**

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

Do not store at a temperature higher than 25 °C. Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton. 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 Faringodol forte contains**

- The active substance is choline salicylate.
- The other ingredients are isomalt (E953), maltitol solution, mint oil (partially dementholised), acesulfame potassium and aspartame (E951).

### **What Faringodol forte looks like and contents of the pack**

Off-white or light yellow cylindrical, slightly biconvex lozenges.

PVC/aluminium foil blister pack in a carton containing 16 or 32 lozenges.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### Marketing Authorisation Holder

Richard Bittner AG

Reisnerstraße 55-57

A-1030 Wien

Austria

#### Manufacturers

GlaxoSmithKline Pharmaceuticals S.A., Grunwaldzka 189, 60-322 Poznan, Poland

or

Przedsiębiorstwo Produkcyjno-Handlowe "EWA" Spółka Akcyjna ul.Zamkowy Folwark 9, 63-700 Krotoszyn, Poland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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**This leaflet was last revised in February 2021.**