



PACKAGE LEAFLET

FARDOBEN 0.15% + 0.12% Oral Spray, Solution

Applied to the inner surface of the mouth and throat (externally).

Active substance: Each bottle (30 ml) contains 36 mg (0.12%) chlorhexidine gluconate, 45 mg (0.15%) benzydamine HCl.

Other ingredients: Sorbitol liquid (non-crystallising) 70%, glycerol, polysorbate 20, peppermint flavor, ethanol 96%, sodium hydrogen carbonate, concentrated hydrochloric acid solution, purified water.

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

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are using this medicine, tell your doctor that you use this medicine when you go to a doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher or lower** dose other than recommended to you.*

In this leaflet:

- 1. What FARDOBEN is and what it is used for**
- 2. What you need to know before you use FARDOBEN**
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- 4. Possible side effects**
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1. WHAT FARDOBEN IS AND WHAT IT IS USED FOR

- FARDOBEN is a clear, colorless or slightly yellow solution. It is available in a 30 ml, white HDPE plastic glass bottle with a pump in a cardboard box. Each box includes 1 bottle.
- FARDOBEN contains chlorhexidine gluconate which has an antimicrobial (killing or preventing the growth of microorganisms) effect and benzydamine HCl which belongs to a group of medicines called non-steroidal anti-inflammatory drugs and is used for the treatment of pain and inflammation and which also exerts local anesthetic effect (causing numbness on application site) when administered topically.
- FARDOBEN is used for inflammatory and painful conditions of oral and throat mucosa such as inflammation of the gums, inflammation inside of the mouth, inflammation of back of the throat, inflammation of the tonsils, mouth sores.
- For preventing microbial diseases causing inflammation in mouth and throat, for relief of patient's swallowing function and as symptom reliever in gum diseases.
- Before and after interventions of gum tissues.
- For inflammation of mucous membranes in the mouth (mucositis) due to radiotherapy, chemotherapy and other reasons.
- For prevention of dental plaques (layer of bacteria and food particles between teeth).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FARDOBEN

DO NOT use FARDOBEN

- If you have known hypersensitivity to benzydamine and chlorhexidine or any of the other ingredients of FARDOBEN.



- If you are pregnant or breastfeeding.
- It should not be used in children 6 years of age and below.

USE SPECIAL CARE with FARDOBEN

- If FARDOBEN comes in contact with eyes, rinse well with plenty of water. FARDOBEN is used only in the mouth; contact with eyes and ears should be avoided.
- Do not swallow FARDOBEN and spit out after each use.
- If sore throat is caused by bacterial infection or accompanied by infection, antibiotic treatment may be required in addition to FARDOBEN use, upon doctor's advice.
- You should use it carefully if you have kidney or liver failure.
- It may cause reversible color change in mouth, on tongue and teeth. Tooth brushing is recommended before application to minimize discoloration.
- It should not be used for more than 7 days continuously.

If these warnings are applicable to you, even for a period in the past, please consult your doctor.

Using FARDOBEN with food and drink

It does not interact with food and drinks.

Pregnancy

Consult your doctor or pharmacist before using this medicine.

Do not use FARDOBEN if you are pregnant or think you may be pregnant.

If you realize you are pregnant during your treatment, immediately consult your doctor or pharmacist.

Breastfeeding

Consult your doctor or pharmacist before using this medicine.

Do not use FARDOBEN if you are breastfeeding.

Driving and using machines

It does not have any effect on the ability to drive and use machines.

Important information about some of the ingredients in FARDOBEN

This medicinal product contains sorbitol. 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 medicinal product contains small amounts of ethanol (alcohol), i.e. less than 100 mg per "dose".

Using other medicines

FARDOBEN does not have any known significant drug interaction.

Chlorhexidine salts, one of the drug substances contained in FARDOBEN, are incompatible with soap and other negatively charged (anionic) compounds, chloramphenicol (type of antibiotic), some inorganic salts and organic compounds; drug interaction with benzydamine has not been reported.

Please tell your doctor or pharmacist if you are using or have recently taken any other medicines, including medicines obtained without a prescription.



3. HOW TO USE FARDOBEN

Instructions for proper use and dose/frequency of administration:

FARDOBEN is directly applied to throat or inflamed area.

The usual dose is 5-10 sprays. It is repeated every 1.5-3 hours as necessary.

It should not be used for more than 7 days continuously.

Route and method of administration:

- FARDOBEN is used without dilution (reconstitution). FARDOBEN should not be swallowed and should be spit out after each use.
- Before the initial use, it should be directed into an area away from the face and pumping button should be pressed couple of times until a fine spray is obtained.
- Mouth should be opened wide; spray nozzle should be put inside the mouth and sprayed into the oral cavity. This procedure should be repeated at different areas at least for 4 times.
- After application, bottle should be placed inside its box and kept in upright position.
- Chlorhexidine in FARDOBEN reduces plaque and gingivitis during treatment. If FARDOBEN is used as an alternative to oral hygiene procedures, FARDOBEN should be held in the mouth at least 1 minute.
- Teeth should be brushed before use in order to minimize the discoloration induced by chlorhexidine in FARDOBEN.

Different age groups

Use in children

In children aged 12 years and above, the spray is applied directly to the throat or inflamed area. The usual dose is 5 sprays. It is repeated every 1.5-3 hours as necessary.

It should not be used in children 6 years of age and below.

Unless recommended by a doctor, it should not be used in children over 6 and under 12 years.

Use in the elderly

The same dose as adults can be applied to the elderly patients.

Use in special conditions

Kidney/Liver failure

It should be used cautiously in patients with severe kidney/liver failure.

If you have the impression that the effect of FARDOBEN is too strong or too weak, talk to your doctor or pharmacist.

If you use more FARDOBEN than you should

Tell a doctor or pharmacist if you have used more FARDOBEN than you should.

Intoxication is not possible considering the method of administration of the drug substance.

However, in case of accidental swallowing of FARDOBEN, your doctor will implement a treatment according to your symptoms.

If you forget to use FARDOBEN

Do not use a double dose to make up for a forgotten dose.

If you stop using FARDOBEN

There is no effect.



4. POSSIBLE SIDE EFFECTS

Like all medicines, FARDOBEN can cause side effects in patients sensitive to its ingredients.

Very common: may occur in at least 1 in 10 patients.

Common : may occur in less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon : may occur in less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare : may occur in less than 1 in 1,000 patients, but more than 1 in 10,000 patients.

Very rare : may occur in less than 1 in 10,000 patients.

Not known : cannot be estimated from the available data.

If any of the following occurs, stop using FARDOBEN and inform your doctor IMMEDIATELY or go to the emergency department of the nearest hospital:

- Sudden shortness of breath, skin rash, swelling of the face and/or tongue
- Hypersensitivity reactions (manifested by cardiac arrest; impaired circulation; low blood pressure; narrowing of the bronchi; palpitations; rash, redness and hives of the skin)
- Allergic reactions (itching, rash, blistering, and hives)

These are all very serious side effects. If you experience any of these side effects, it indicates that you have serious allergy to FARDOBEN. You may need urgent medical intervention or hospitalization. These very serious side effects occur very rarely.

If you experience any of the following, tell your doctor:

Very common

- Numbness in mouth

Common

- Tingling and burning sensations of the mouth
- Nausea, vomiting, retching
- Altered taste
- Staining of teeth and other oral surfaces (tooth staining is harmless and can be minimized through tooth brushing before application)
- Increase in tartar formation

Rare

- Sensations of burning and stinging

Very rare

- Local (regional) dryness or thirst, aching
- Feeling of coolness in the mouth
- Allergic reactions, hypersensitivity and anaphylaxis (sudden shortness of breath, skin rash, swelling of the face and/or tongue)
- Laryngospasm (involuntary muscle contraction of the larynx), bronchospasm (narrowing of the airways)
- Temporary swelling and enlargement of the salivary glands
- Irritation-related skin reactions, itching accompanied by rash, hives, photodermatitis (light-induced skin reaction), dandruff, peeling
- Oral desquamation



Not known

- Dizziness, headache, drowsiness
- Pharynx irritation (irritation of the esophagus), cough
- Dry mouth

These are mild side effects of FARDOBEN.

These side effects disappear when the dose is reduced or treatment is stopped.

If you experience any side effect not mentioned in this package leaflet, inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. 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 FARDOBEN

Keep FARDOBEN out of the reach and sight of children and in its original package.

Store at room temperature below 25°C and protected from light.

Use the medicine in accordance with its expiry date.

Do not use FARDOBEN after the expiry date stated on the label or package.

Do not use FARDOBEN if you notice any damage on the product and/or its package.

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.

Marketing Authorization Holder:

DEVA Holding A.Ş.
Küçükçekmece – İSTANBUL / TÜRKİYE

Manufacturing Site:

DEVA Holding A.Ş.
Kapaklı – TEKİRDAĞ / TÜRKİYE

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