



PACKAGE LEAFLET

FARDOBEN 0.15% + 0.12% Gargle

To be used as mouth rinse and/or gargle.

Active substance: Each 5 mL solution (1 dose) contains 6 mg (0.12%) chlorhexidine gluconate and 7.5 mg (0.15%) benzydamine hydrochloride.

Excipients: Sorbitol liquid (non-crystallizing) 70%, glycerin, polysorbate 20, peppermint flavor, ethanol 96%, vaporboost flexarome, sodium bicarbonate, hydrochloric acid, 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 a **lower** dose other than recommended to you.*

In this leaflet:

- 1. What FARDOBEN is and for what it is used***
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1. WHAT FARDOBEN IS AND FOR WHAT IT IS USED FOR

- FARDOBEN is an oral product used in the mouth for local treatment.
- FARDOBEN is a colorless or yellowish clear solution. It is presented in an amber-colored glass bottle of 200 mL. Each cardboard box contains 1 bottle and a measuring cup marked at 5 ml, 10 ml, 15 ml and 20 ml.
- FARDOBEN contains chlorhexidine gluconate which has an antimicrobial effect (killing or preventing the growth of microorganisms) and contains 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 a local anesthetic effect (causing numbness on application site) in case of topical use.

FARDOBEN is used:

- For inflammatory and painful conditions of mouth and throat mucosa such as inflammation of the gums, inflammation inside of the mouth, inflammation of back of the throat, inflammation of the tonsils, and 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 on 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 in the following situations:

- If you have a known hypersensitivity to benzydamine or chlorhexidine or to any of the excipients of this medicinal product.
- If you are pregnant or breastfeeding.
- In children 6 years of age and below.

USE FARDOBEN CAREFULLY in the following situations:

- FARDOBEN is for mouth rinse or gargle; do not swallow.
- It is used only in the mouth; its contact with eyes and ears should be avoided.
- It may cause reversible color change in mouth, on tongue and teeth. Tooth staining is harmless and can be minimized through tooth-brushing before application.
- FARDOBEN should not be swallowed and should be spit out after each use. It is used without dilution.
- If sore throat is caused by bacterial infection or accompanied by infection, antibacterial treatment can be considered in addition to FARDOBEN use.
- If you have kidney or liver disorders.
- It should not be used for longer than 7 days in the event of uninterrupted use.

If these warnings apply 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 beverages due to its route and method of application.

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 notice that you are pregnant during your treatment, contact your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medicine.

Do not use FARDOBEN if you are breast-feeding.

Driving and using machines

There is no adverse effect on driving and using machines.

Important information about some of the ingredients in FARDOBEN

This product contains ethanol (alcohol) up to 9.5% by volume; for example, up to 1123.2 mg per dose (15 mL), equivalent to 28.5 mL beer per dose, equivalent to 11.9 mL wine per dose. It can be harmful for those with alcohol addiction.

It should be taken into consideration in children, pregnant or breastfeeding women, and patients at high risk, such with liver disease or epilepsy.

This product contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, ask your doctor before using FARDOBEN.



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 (a type of antibiotic), some inorganic salts and organic compounds. No drug interactions with benzydamine have 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

The adult dose of FARDOBEN is 15 ml and is applied at 1.5-hour to 3-hour intervals throughout the day. Duration of use should not exceed 7 days if applied without interruption.

Route and method of administration

FARDOBEN is for mouth rinse or gargle. It should be applied undiluted and kept in the mouth for at least 30 seconds, then spit out after each application.

The chlorhexidine substance contained in FARDOBEN reduces plaque and inflammation in the gums during the treatment. If FARDOBEN is used as an alternative to oral hygiene procedures, the mouth should be rinsed with FARDOBEN for at least 1 minute. Teeth should be brushed before using the product in order to minimize the discoloration caused by chlorhexidine.

Different age groups

Use in children

For children 12 years of age and above, it is recommended to gargle with 5 ml to 15 ml of FARDOBEN for 30 seconds every 1.5 hours to 3 hours.

This medicinal product is not for use in children 6 years of age and below.

Do not use in children aged over 6 and under 12 years unless told by the doctor.

This medicinal product should not be used for longer than 7 days continuously.

In case of burning and stinging sensation, the gargle should be diluted with water.

Use in the elderly

No dosage adjustment is required in the elderly.

Use in special conditions

Kidney / Liver failure

Impaired kidney function: As absorbed benzydamine and its metabolites are eliminated via urine, possibility of systemic effect should be taken into consideration in patients with severe kidney impairment.

Impaired liver function: As absorbed benzydamine is metabolized highly in liver, possibility of systemic effect should be taken into consideration in patients with severe liver impairment.

Follow these instructions unless your doctor gives specific advice. Do not forget to take your medicine on time.

Your doctor will explain to you how long your treatment will last with FARDOBEN. Do not stop your treatment early because then you cannot get the desired result.

If you have an 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 use more FARDOBEN than you should.

In case of accidental swallowing of FARDOBEN, symptomatic treatment should be instituted. There is no specific antidote.

If you forget to use FARDOBEN

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

If you stop using FARDOBEN

No effects are expected.

4. POSSIBLE SIDE EFFECTS

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

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

- Sudden shortness of breath, skin rash, swelling of the face and/or tongue (anaphylaxis)
- Hypersensitivity reactions (cardiac arrest, circulatory disorder, decrease in blood pressure, narrowing of the bronchi, palpitation, skin rash with redness and hives)
- Allergic reactions (itching, rash, blisters, hives)

These are 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 attention or hospitalization. These very serious side effects occur very rarely.

Side effects are classified in the following frequencies:

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.

Tell your doctor if you notice any of the following:

Very common

- Numbness in the mouth

Common

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

Rare

- Burning and stinging sensation in the mouth



Very rare

- Local (topical) dryness or thirst, tingling
- 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 in the larynx), bronchospasm (narrowing of the airways)
- Transient swelling and/or enlargement of the salivary glands
- Irritation-related skin reactions, itching with rash, hives, photodermatitis (reaction on the skin due to light), dandruff, peeling
- Oral desquamation

Unknown

- Dizziness, headache, drowsiness
- Irritation of the pharynx, cough
- Dryness of the mouth

These are mild side effects of FARDOBEN. These side effects disappear when the dose is reduced or treatment is stopped.

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.

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

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 protect from light.

Use the medicine in accordance with its expiry date.

Do not use FARDOBEN after the expiry date indicated on packaging.

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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