

PATIENT INFORMATION LEAFLET

ANDOREX Gargle For mouth wash.

Active substance: 200 ml solution contains 240 mg (0.12%) chlorhexidine digluconate and 300 mg (0.15%) benzydamine hydrochloride.

Excipients: Sorbitol (70%) (E420), glycerol, polysorbate 20, ethanol 96%, tartrazine (E102), peppermint essence, patent blue, purified water.

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

This non-prescription drug aims to provide treatment for your diseases through the recommendation of your pharmacist without the aid of a physician. However, you need to use cautiously in order to have the best results from ANDOREX.

- *Keep this leaflet. You may need to read it again.*
- *If you have further questions, ask your doctor or pharmacist.*
- *Please state that you are using this drug if you visit a physician or hospital during the administration of this drug.*
- *Please follow the instructions here precisely. Do not take **higher or lower** dose other than the recommended.*

What is in this leaflet:

1. *What ANDOREX is and what it is used for?*
2. *What you need to know before you take ANDOREX?*
3. *How to use ANDOREX?*
4. *Possible side effects*
5. *How to store ANDOREX?*

1. **What ANDOREX is and what it is used for?**

- ANDOREX is an oral preparation used for local oral treatment.
- ANDOREX is green and clear solution with mint taste and scent. It is contained in 200 ml Amber plastic bottles together with 15 ml measuring cup, in cardboard box. Each box holds 1 pcs 200 ml gargle.
- ANDOREX is content a chlorhexidine gluconate that called an antimicrobial (killing microbes or stopping proliferation) active and benzydamine HCl that called substance non-steroidal anti-inflammatory, and is used in the treatment of pain and inflammation (inflammation), as well as local anesthetic when applied superficially (which leads to numbing of the applied region).
- ANDOREX, inflammation of the mouth and throat, inflammation of the gingiva with inflammation and pain, inflammation of the mouth, inflammation of the pharynx, inflammation of the tonsils,
- ANDOREX is used for the prevention of microbial disorders causing inflammation in the mouth and throat, relieving the deglutition and elimination of symptoms

gingiva disorders. In dentistry, it may be used for protection purposes before the operations.

- Before and after the operations in the tissues surrounding the teeth,
- In the treatment of inflammation of the oral cavity (mucositis) due to radiation therapy and cancer drug treatment or other causes,
- It is used to prevent the layer (dental plaque) formed by bacteria and food debris around the teeth.

**2. What you need to know before you take ANDOREX? DO NOT USE
ANDOREX in the following conditions**

If;

- you have hypersensitivity to benzydamine and chlorhexidine or any known substance contained in ANDOREX,
- you are pregnant or breastfeeding.

TAKE ANDOREX CAUTIOUSLY in the following cases.

- It is only for gargling; do not swallow.
- Due to the absence of sufficient number of clinical studies ANDOREX is not recommended for children under 12 years old.
- Only use orally; avoid contact with eyes and ears.
- It may lead to reversible color change in the mouth, on the tongue and teeth. Staining on the teeth is harmless and it can be minimized by brushing.
- ANDOREX should not be swallowed and expurged through expuition. It is used undiluted.
- If sore throat is due to bacterial infection or accompanied by an infection, anti-bacterial treatment may be considered in addition to ANDOREX use by your doctor.
- If you have renal and liver disease.

If these warnings are included in any period as well in the past for you, please consult your doctor.

Taking ANDOREX with food and beverage

It does not have interaction with food and beverages in consideration of its application method.

Pregnancy

Consult your doctor or pharmacist before taking the drug.

If you are pregnant, do not use ANDOREX. Do not use ANDOREX if you are pregnant or think you may be pregnant.

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

Breast-feeding

Consult your doctor or pharmacist before taking the drug.

If you are breast feeding, do not use ANDOREX.

Driving and using machines

No side effect is expected on driving and using machines.

Important information about some ingredients of ANDOREX

Because of the sorbitol it contains, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ANDOREX.

This medicinal product contains small amounts of ethanol (alcohol) – less than 100 mg (1.5 ml) per dose.

The tartrazine contained in this medicinal product may cause an allergic reaction.

Administration in combination with other drugs

ANDOREX has no known significant drug interaction.

ANDOREX is content with chlorhexidine salts, soap and other minus charged (anionic)

compounds, chloramphenicol (antibiotic species), certain inorganic salts and organic compounds; no drug interactions have been reported with benzydamine.

Tell your doctor or pharmacist if you are taking or recently have taken any other medicines that you buy with or without a prescription.

3. How to use ANDOREX?

Instructions for appropriate use and dosing/administration frequency:

Adult dose for ANDOREX is 15 ml. It is administered with 1.5-3-hour intervals throughout the day.

Route and method of administration:

ANDOREX is used to rinse mouth and gargle. ANDOREX is used undiluted. It is kept in the mouth for at least 30 seconds. It is expurged from mouth after use.

Chlorhexidine contained in the ANDOREX reduces plaque and gingivitis during the course of the treatment. If ANDOREX is used as an alternative to other oral cleaning applications, the mouth should be rinsed with ANDOREX for at least 1 minute. In order to minimize coloration caused by chlorhexidine in ANDOREX it is advised to brush your teeth before administration.

Various age groups:

Use in children (12-year old and over):

Gargle for 30 seconds every 1.5-3 hours with 5-15 ml ANDOREX. It should not be continuously used for more than 7 days.

Gargle should be diluted with water in case of burning and stinging sensation.

Due to the absence of sufficient number of clinical studies use of ANDOREX is not recommended for children under 12 years old.

Use in elders:

No dose change is required for elder people.

Administration under special conditions:

Renal failure/Liver failure:

It should be used with caution in patients with severe renal or hepatic impairment.

Unless your doctor recommends otherwise follow these instructions. Do not forget to take your medicine on time.

Your doctor will tell you how long your treatment will take with ANDOREX. Do not stop treatment early because you will not get the desired result.

If you have an impression about effect of ANDOREX that it is strong or weak, talk to your doctor or pharmacist.

If you take more amount of ANDOREX than you should

If you take more amount of ANDOREX than you should, consult a physician or pharmacist.

If ANDOREX is drunk by mistake, treatment should be made according to the symptoms. There is no specific antidote.

If you forget to take ANDOREX

Do not take double doses to compensate the doses you have missed.

Potential effects of discontinuation of ANDOREX therapy

No effect is expected.

4. Possible side effects

Like all medicines, patients with sensitivity to the ingredients of ANDOREX may cause side effects.

If any of the following occur, stop using ANDOREX and tell your doctor or your emergency department of your nearest hospital:

- Sudden shortness of breathing, rash on the face, swelling of the face and / or the ankle (anaphylaxis)
- Hypersensitivity reactions (hypersensitivity) (cardiac arrest, circulatory disorders, drop in blood pressure, narrowing of the bronchi, palpitations, skin rash, rash and hives)
- Allergic reactions

These are very serious side effects. If one of these side effects exists in you, then you have a serious allergy to ANDOREX. You may need to be admitted to an emergency medical intervention or hospital.

These very serious side effects are very rare.

Side effects are listed as shown in the following categories:

Very common: More than one in 10 patients can be seen.

Common: less than one in 10 patients but more than one in 100 patients.

Uncommon: less than one in 100 patients but more than one in 1000 patients.

Rare: less than one in 1.000 patients but more than one in 10.000 patients.

Very rare: may be seen less than one in 10.000 patients.

Unknown: It can be seen in a small number of patients that cannot be determined by the available data.

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

Very common:

- Numbness in mouth tissue

Common:

- Pinching and burning sensation in the mouth
- Nausea, vomiting, retching
- Change in taste
- Staining on teeth and other oral surfaces (Tooth staining is harmless and can be minimized by brushing teeth before application.)
- Increase in tartar formation

Rare:

- Burning and stinging sensation

Very rare:

- Local (regional) dryness or thirst, tingling
- A feeling of coolness in the mouth
- Allergic reactions, hypersensitivity (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)
- Temporary swelling and enlargement of the salivary glands
- Skin reactions due to irritation, itching with rash, hives, photodermatitis (skin reaction due to light), dandruff, peeling
- Oral desiccation

Unknown:

- Dizziness, headache, drowsiness
- Pharyngeal irritation (irritation of the pharynx), cough
- Dry mouth

These are mild side effects of CHLOREMINE. These side effects disappear when the dose is reduced or treatment is discontinued.

If you experience any adverse effects that are not included in this patient information leaflet, talk to your doctor or pharmacist about this.

Reporting of side effects

If you get any side effects, stated or not stated in the Patient Information Leaflet, talk to your doctor or pharmacist. Also, please report the side effects you have to Turkish Pharmacovigilance Center (TÜFAM) by either clicking to “Reporting Drug Side Effect” icon on www.titck.gov.tr or calling side effect reporting line via 0 800 314 00 08. By reporting the side effects you can help provide more information on the safety of this medicine.

TÜFAM	Turkish Pharmacovigilance Center www.titck.gov.tr
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5. How to store ANDOREX?

Keep ANDOREX in its package and out of sight and reach of children.

Keep at room temperature below 25 °C.

Use in accordance with the date of expiry.

Do not use ANDOREX after the date of expiry mentioned on the package.

If you notice any defects in the product and/or packaging do not use ANDOREX.

“Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization. ”

Marketing Authorization Holder:

Humanis Saglik A.S.
Mahmutbey Mahallesi, Tasocagi Yolu
Caddesi, Solen Residance Apt. No:19/1/11
Bagcilar/Istanbul/TURKEY

Manufacturer:

Humanis Saglik A.S.
Karaagac Mah., Fatih Blv., No:32 Cerkezkoy Organize Sanayi Bolgesi-
Kapakli/Tekirdag/TURKEY

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