ANDOREX %0.15+%0.12 spray, solution

Applied to the inner surface of the mouth and throat (topical). · License No: ANDOREX · ATC: A01AD02

Prescription-only	Antiseptic and local anesthetic	Benzydamine HCl, Chlorhexidine Gluconate	Not for use under 6 years of age

ACTIVE INGREDIENT

One spray (0.2 ml) contains 0.30 mg benzydamine hydrochloride and 0.24 mg chlorhexidine gluconate.

EXCIPIENTS

Peppermint oil, sorbitol (E420), Patent Blue V, glycerol, polysorbate 20, tartrazine (E102), ethanol, purified water

PACKAGING

30 ml white plastic bottle with oral applicator

INSTRUCTIONS FOR USE

Please read these INSTRUCTIONS FOR USE carefully before you start using this medicine, as they contain important information for you.

- Keep these instructions. You may need to read them again later.
- If you have further questions, please consult your doctor or pharmacist.
- This medicine has been prescribed for you personally, do not give it to others.
- During the use of this medicine, when you go to a doctor or hospital, tell your doctor that you are using this medicine.
- Follow these instructions exactly. Do not use a dose **higher or lower** than the dose recommended to you for this medicine.

IN THESE INSTRUCTIONS FOR USE:

What is ANDOREX and what is it used for?

ANDOREX Spray is a clear green, peppermint-scented solution spray. It is available in a 30 ml white plastic bottle with an oral applicator (special nozzle for oral application).

ANDOREX contains chlorhexidine gluconate, an antimicrobial agent (kills or stops the proliferation of microbes), and benzydamine HCl, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs, used in the treatment of pain and inflammation, and also has a local anesthetic effect (provides numbness in the applied area) when applied topically.

Indications

INDICATION 1

Inflammation of Oral and Pharyngeal Mucosa

Gingivitis, stomatitis, pharyngitis, tonsillitis, and ulcers observed in the mouth.

INDICATION 2

Prevention of Microbial Diseases

Prevention of microbial diseases causing inflammation in the mouth and throat, relief of swallowing function, and alleviation of symptoms in gum diseases.

INDICATION 3

Peridental Procedures

Before and after procedures involving tissues surrounding the teeth.

INDICATION 4

Mucositis after Drug Treatment

In mucositis (inflammation of the oral lining) after radiation therapy and cancer drug treatment or due to other causes.

INDICATION 5

Prevention of Dental Plaque

In the prevention of dental plaque, a layer formed by bacteria and food residues around the teeth.

Things to consider before using ANDOREX

DO NOT use ANDOREX in the following situations

Do not use if you are hypersensitive to benzydamine and chlorhexidine or any of the ingredients in ANDOREX.

Do not use ANDOREX if you are pregnant or breastfeeding.

Should not be used in children aged 6 years and under.

USE ANDOREX CAREFULLY in the following situations

If,

If ANDOREX comes into contact with the eyes, rinse immediately and thoroughly with plenty of water. ANDOREX is for oral application only; avoid contact with eyes and ears.

Do not swallow ANDOREX and remove it from the mouth by spitting.

If sore throat is caused by bacterial infection or occurs with infection, antibiotic treatment may be necessary in addition to ANDOREX use, as advised by your doctor.

If you have kidney or liver impairment, you should use it with caution.

It may cause reversible discoloration on the inside of the mouth, tongue, and teeth. To minimize discoloration, it is recommended to brush your teeth before use.

Should not be used for more than 7 consecutive days.

If these warnings apply to you at any time, please consult your doctor.

Using ANDOREX with food and drink

There is no interaction with food and drink.

> **Pregnancy**
>
> *Consult your doctor or pharmacist before using the medicine.*
>
> Do not use ANDOREX if you are pregnant or think you might be pregnant.
>
> *If you discover you are pregnant during your treatment, consult your doctor or pharmacist immediately.*

> **Breastfeeding**
>
> *Consult your doctor or pharmacist before using the medicine.*
>
> Do not use ANDOREX if you are breastfeeding your baby.

Driving and using machines

There is no negative effect on driving and using machines.

Important information about some excipients in ANDOREX

Due to 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 a small amount of ethanol (alcohol) – less than 100 mg (0.02 mL) per dose.

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

Using with other medicines

ANDOREX has no known significant drug interactions.

Salts of chlorhexidine, one of the active ingredients in ANDOREX, are incompatible with soaps and other anionic compounds, chloramphenicol (an antibiotic type), some inorganic salts, and organic compounds; no drug interactions have been reported with benzydamine.

If you are currently using or have recently used any prescription or non-prescription medicine, please inform your doctor or pharmacist about them.

How to use ANDOREX?

Instructions for proper use and dose / frequency of administration:

ANDOREX is applied directly to the throat or the inflamed area. The general dose is 5-10 sprays. If necessary, it can be repeated every 1.5 - 3 hours. It should not be used for more than 7 consecutive days.

Method and route of administration:

Please follow the instructions below for using ANDOREX.

1. Raise the spray tube until it is in a horizontal position (90 degrees) as shown in Figure 1.
2. Before first use, point away from the face (towards the air) and press the pump button several times until a regular spray is

obtained. **If a regular spray is not achieved or the spray tube is displaced, do not use the product and return it to your pharmacist.**

3. After the first spray, which you perform away from your face with the spray tube, the spray will be ready for use.
4. As indicated in Figure 2, hold the **bottle and your head upright**, point the spray nozzle into your mouth or throat, and press the spray button.
5. After the desired number of sprays has been applied, return the spray tube to its original position and store it in its box.

ANDOREX is used undiluted. ANDOREX should not be swallowed and should be removed from the mouth by spitting.

Before first use, point away from the face and press the pump button several times until a regular spray is obtained.

The mouth should be opened wide, and the spray nozzle should be inserted into the mouth and sprayed into the oral cavity. This process should be repeated at least 4 times in different areas.

After application, the bottle should be placed in its box and stored upright.

The chlorhexidine contained in ANDOREX reduces plaque and gingivitis formation during treatment. If used as an alternative to oral hygiene methods, ANDOREX should be held in the mouth for at least 1 minute.

To minimize discoloration caused by chlorhexidine in ANDOREX, it is advisable to brush teeth before use.

Different age groups: Use in children:

In children aged 12 years and over, the spray is applied directly to the throat or the inflamed area. The general dose is 5 sprays. If necessary, it can be repeated every 1.5 - 3 hours. Should not be used in children aged 6 years and under.

In children between 6 and 12 years of age, the product should not be used unless advised by a doctor.

Use in the elderly:

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

Special use cases:

Kidney / Liver failure:
Should be used with caution in patients with severe kidney or liver failure.

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

If you have used more ANDOREX than you should:

If you have used more ANDOREX than you should, talk to a doctor or pharmacist immediately.

Poisoning is not possible given the route of administration of the active substance.

However, if ANDOREX is accidentally ingested, your doctor will provide symptomatic treatment.

If you forget to use ANDOREX

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

Effects that may occur when treatment with ANDOREX is discontinued

None.

What are the possible side effects?

Like all medicines, ANDOREX may cause side effects in people sensitive to its ingredients.

Very common: May be seen in at least 1 in 10 patients.

Common: May be seen in less than 1 in 10 patients but more than 1 in 100 patients.

Uncommon: May be seen in less than 1 in 100 patients but more than 1 in 1,000 patients.

Rare: May be seen in less than 1 in 1,000 patients but more than 1 in 10,000 patients.

Very rare: May be seen in less than 1 in 10,000 patients.

Unknown: Cannot be estimated from the available data.

> **If any of the following occur, stop using ANDOREX and IMMEDIATELY notify 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.
>
> Hypersensitivity reactions (characterized by cardiac arrest, circulatory failure, hypotension, bronchospasm, palpitations, skin rash, redness, and hives).
>
> Allergic reaction (itching, rash, blisters, hives).
>
> These are very serious side effects. If you experience any of these side effects, it means you have a severe allergy to ANDOREX. You may need urgent medical intervention or hospitalization.
>
> These very serious side effects are seen very rarely.

Tell your doctor if you notice any of the following.

Very common:

Numbness in oral tissues

Common:

Prickling 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.)

Increased calculus formation

Rare:

Burning and stinging sensation

Very rare:

Local dryness or thirst, tingling

Cooling sensation 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 airways)

Temporary swelling, enlargement of salivary glands

Irritation-related skin reactions, itching with rash, hives, photodermatitis (skin reaction due to light), flaking, peeling

Oral desquamation

Unknown:

Dizziness, headache, drowsiness

Pharyngeal irritation (throat irritation), cough

Dry mouth

These are mild side effects of ANDOREX.

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

Reporting of side effects

If you experience any side effects, whether or not listed in these Instructions for Use, talk to your doctor, pharmacist, or nurse. You can also contribute to obtaining more information about the safety of the medicine you are using by reporting any side effects you experience to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effect Notification" icon on www.titck.gov.tr or by calling the side effect notification line at 0 800 314 00 08.

If you experience any side effects not mentioned in these instructions for use, inform your doctor or pharmacist.

How to store ANDOREX?

Store ANDOREX out of the sight and reach of children, and in its packaging.

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

Use in accordance with the expiration date

Do not use ANDOREX after the expiration date stated on the label or packaging.

Do not use ANDOREX if you notice any defects in the product and/or its packaging.

Environmental Protection

"Do not dispose of expired or unused medicines in the trash! Deliver them to the collection system specified by the Ministry of Environment, Urbanization and Climate Change."

License holder:

Humanis Sağlık A.Ş Maslak/Sarıyer/İstanbul

Manufacturing site:

Humanis Sağlık A.Ş. Kapaklı/Tekirdağ

These instructions for use were approved on 24.10.2023.