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Benzydamine hydrochloride Chlorhexidine digluconate

Solmux® Throat *Spray*

1.5 mg / 1.2 mg per mL Oromucosal Spray
Nonsteroidal Anti-inflammatory Drug (NSAID) / Antiseptic

FORMULATION
Each mL oromucosal spray contains:
Benzydamine hydrochloride……..…… 1.5 mg
Chlorhexidine digluconate……..…… 1.2 mg

PRODUCT DESCRIPTION

Dosage Strength and Format	Manufacturer	Product Description
1.5 mg / 1.2 mg per mL Oromucosal Spray	Humanis Sağlık Anonim Şirketi, Turkey	Green-colored, clear solution with peppermint odor. It comes in a 30 mL HDPE bottle with a spray pump and polypropylene applicator.

WHAT IS IN THE MEDICINE?
This medicine contains benzydamine and chlorhexidine.

Benzydamine is a locally acting nonsteroidal anti-inflammatory drug that reduces inflammation and provides fast relief from symptoms of irritation caused by infection such as swelling, redness and pain.

Chlorhexidine is a local antiseptic agent which kills viruses and bacteria in the mouth and throat that cause infections like tonsillitis (inflammation of the tonsils), pharyngitis (inflammation of the pharynx), laryngitis (inflammation of the larynx), thereby also preventing the worsening of symptoms such as cough, colds, pain, swelling and sore/itchy throat including COVID and other infections of the upper respiratory tract triggering symptoms of allergy and flu.

A clinical study by Huang, et al. demonstrated that the use of chlorhexidine as an oral rinse and mouth spray eliminated 86% of oropharyngeal severe acute respiratory syndrome coronavirus (SARS-CoV) 2 versus control.

STRENGTH OF THE MEDICINE
See Formulation

WHAT IS THE MEDICINE USED FOR?
This medicine is used for the relief of painful inflammatory conditions of the throat including:
- Traumatic conditions: Pharyngitis following tonsillectomy or the use of a nasogastric tube
- Inflammatory conditions: Tonsillitis, sore throat, pharyngitis, aphthous ulcers and oral ulceration due to radiation therapy
- Dentistry: For use after dental operations

It is also used as a local antiseptic.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
This medicine should be directly administered in the throat or inflamed area.

Age Group	Recommended Dose
Adults and Children 12 years and older	2 to 4 sprays directly onto the sore/inflamed area. Repeat every 1 ½ to 3 hours as necessary.
Children 6 to 12 years	2 sprays directly onto the sore/inflamed area. Repeat every 1½ to 3 hours as necessary.
	Or, as directed by a doctor.

- Each spray (0.2 mL) contains 0.30 mg of benzydamine hydrochloride and 0.24 mg chlorhexidine digluconate.
- Do not administer in children below 6 years old.
- For symptomatic and short-term use only. Uninterrupted treatment should not exceed 7 days, unless under medical supervision. It should not be used without consulting a doctor if sore throat is severe or has lasted for more than 2 days or is accompanied by high fever, headache, nausea or vomiting.

Method of administration:
- This medicine is used undiluted (without adding water). It should not be swallowed and should be expectorated after each use.
- Before first use, the pumping switch should be pressed until a uniform spraying is achieved by directing away from the face.
- Tip of the spray should be inserted in the mouth and sprayed into the oral cavity when the mouth is fully opened.
- Upon administration, the medicine should be placed in the box of the bottle and stored in vertical direction.

Special Instructions:
- Avoid contact with the eyes and ears. If the medicine comes in contact with the eyes, wash the eyes with water immediately.
- This medicine may lead to reversible color change in the mouth, on the tongue and teeth due to its chlorhexidine content. In order to minimize discoloration, brushing of the teeth is advised before administration.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
- If you are allergic to benzydamine, chlorhexidine or to any ingredient in the product
- If you pregnant or breastfeeding

UNDESIRABLE EFFECTS

Benzydamine
Immune system disorders: Anaphylactic reactions (rare, life-threatening allergic reaction), angioedema (deep swelling around the eyes and lips and sometimes of the hands and feet), hypersensitivity
Psychiatric disorders: Drowsiness
Nervous system disorders: Dizziness, headache
Respiratory, thoracic, and mediastinal disorders: Bronchospasm (narrowing of airways in the lungs), cough, laryngospasm (sudden, uncontrolled cramp in the voice box)
Gastrointestinal disorders: Dry mouth, dysgeusia (taste disturbance), nausea, numbness or stinging sensation of the oral mucosa, retching, tooth discoloration, vomiting
Skin and subcutaneous tissue disorders: Erythema (redness), photosensitivity, rash, pruritus (itching), urticaria (itchy rash)
General disorders and administration site conditions: Thirst

Chlorhexidine
Immune system disorders: Anaphylaxis (rare, life-threatening allergic reaction) and hypersensitivity
Nervous system disorders: Ageusia (absence of sense of taste), glossodynia (burning or tingling sensation in or around the mouth), hypoesthesia (reduced sensation to touch, pain and temperature), paresthesia (sensation of tingling, pricking or numbness of the skin)
Gastrointestinal disorders: Coated tongue, dry mouth, dysgeusia (taste disturbance), desquamation/swelling of the oral mucosa, discoloration of the teeth and tongue, gingivitis

(inflammation of the gums), glossitis (inflammation of the tongue), mucocele (dilatation of a cavity with accumulated mucus secretion), sialadenosis (disease of a salivary gland), irritation of the mouth, parotid gland swelling
Skin and subcutaneous tissue disorders: Erythema (redness), generalized allergic reactions

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

Benzydamine
There are no known interactions with benzydamine.

Chlorhexidine
Chlorhexidine is incompatible with other anionic compounds.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If you miss a dose, just administer the next dose if still needed for the condition being treated, and the subsequent doses at the recommended time or schedule.

Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?

Manufacturer	Storage Conditions
Humanis Sağlık Anonim Şirketi, Turkey	Store at temperatures not exceeding 30ºC. Protect from light. Keep the product out of sight and reach of children.

SIGNS AND SYMPTOMS OF OVERDOSAGE

Benzydamine
Intoxication is only expected in case of accidental ingestion of large quantities of benzydamine (>300 mg).
Signs and symptoms of benzydamine overdose include nausea, vomiting, abdominal pain, esophageal irritation, dizziness, hallucinations, agitation, anxiety, and irritability.

Chlorhexidine
Chlorhexidine is poorly absorbed from the gastrointestinal tract and serious poisoning from ingestion is unlikely.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?
If you have used more than the recommended dosage, consult a doctor.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE
- Use with caution if you have renal (kidney) or liver disorders.
- If sore throat occurred with bacterial inflammation or accompanied by an inflammation, antibiotic treatment upon medical advice may be required in addition to the use of this medicine.
- This medicine contains FD&C Yellow #5 (tartrazine) which may cause allergic reactions (including bronchial asthma) in certain susceptible individuals.
- This medicine contains alcohol in small amounts (less than 100 mg per dose).
- Do not use more than the recommended dose.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
Stop administering the medicine and consult your doctor immediately if you develop any of the following:
- Shortness of breath, skin rash, swelling on the face and/or tongue
- Hypersensitivity reactions
- Allergic reactions
- Skin reactions due to irritation
- Rash in the mouth
- Throat irritation and cough
- Growing of salivary gland

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at +632-8-**UNILAB**-1 (+632-8-**864522**-1) for Metro Manila or toll-free +1-800-10-UNILAB-1 for provinces, or e-mail productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY: Available in White HDPE Bottle with Plastic Spray Pump and PP Applicator x 30 mL
DATE OF FIRST AUTHORIZATION: November 2023
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