SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Benzydamine Hydrochloride 0.30 % w/v Oromucosal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 3 mg of benzydamine hydrochloride. Each spray is equal to 0.18 ml solution. Excipients with known effect:

Benzyl alcohol 0.0648 µg in spearmint flavor per spray

Methyl parahydroxybenzoate 0.18 mg as per spray

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oromucosal spray, solution

Colorless and clear solution with mint odor.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of painful inflammatory and swelling conditions of the mouth and throat,

e.g. Infections, laryngitis, radiomucositis and postoperative conditions.

4.2 Posology and method of administration

Dosage

Benzydamine Hydrochloride 0.30 % w/v Oromucosal Spray is generally used 2 to 6 times daily (every 1 ½ -3 hours):

Adults and adolescents over 12 years 2 - 4 sprays. 1 ½ -3 hourly

Children between 6 and 12 Years 2 sprays. 1 ½ -3 hourly

Children under 6 years with bw over 8 kg

1 spray per 8 kg body weight, maximum 2 sprays, 1 ½ -3 hourly

Elderly patients

There are no specific recommendations for dosing in elderly patients. Unless prescribed otherwise by the dentist or doctor, the dosage indicated for adults is valid.

Benzydamine Hydrochloride 0.30 % w/v Oromucosal Spray is used for mouth and throat.

Instructions for Use:

1. On first use, press the pump button several times until you get a regular spray,

2. Open your mouth thoroughly and guide the spray tube into your diseased area by inserting into your mouth,

3. Quickly press the pump button to spray the medicine; repeat this process with the numbers mentioned above,

4. Keep the bottle in box and store standing upright.

4.3 Contraindications

Hypersensitivity to active substance benzydamine hydrochloride or any of the excipients listed in section 6.1.

Benzydamine Hydrochloride 0.30 % w/v Oromucosal Spray should not be used in infants and children up to 2 years due to the content of menthol (peppermint aroma).

4.4 Special warnings and precautions for use

If any of the adverse effects mentioned above occur, the preparation should be temporarily discontinued. Use of the product, especially for a long time, can lead to sensitization. In this case, the preparation should be discontinued temporarily and a physician should be contacted.

In a limited number of patients, mouth and throat ulcers can be signs of more serious diseases. Patients who do not get better within 3 days must contact their doctor or dentist in this regard.

In patients who are hypersensitive to salicylic acid or other NSAIDs, application of benzydamine is not recommended.

The indications do not justify long-term treatment, as this could affect the normal bacterial flora of the oral cavity.

Benzydamine Hydrochloride 0.30 % w/v Oromucosal Spray should be used with caution in patients with a history of bronchial asthma, since bronchospasm may occur.

This medicine contains methyl p-hydroxybenzoate (E 218), which may cause allergic reactions (possibly delayed).

This medicinal product contains benzyl alcohol. Benzyl alcohol may cause mild local irritation.

4.5 Interaction with other medicinal products and other forms of interaction

No studies were conducted to assess interactions.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is limited amount of data from the use of benzydamine hydrochloride in pregnant women. There is no evidence of a teratogenic effect in animal studies (see section 5.3). Benzydamine Hydrochloride 0.30 % w/v Oromucosal Spray should not be used in pregnancy unless the clinical condition of the woman requires treatment with benzydamine hydrochloride.

Breast-feeding

It is unknown whether benzydamine hydrochloride /metabolites are excreted in human milk. Benzydamine Hydrochloride 0.30 % w/v Oromucosal Spray should not be used during breastfeeding unless considered essential by the physician.

Fertility

There is no evidence of fertility effects from animal studies (see section 5.3). It is not known whether treatment with Benzydamine Hydrochloride 0.30 % w/v Oromucosal Spray can affect fertility in humans.

4.7 Effects on ability to drive and use machines

Benzydamine Hydrochloride 0.30 % w/v Oromucosal Spray has no influence on the ability to drive and operate machines.

4.8 Undesirable effects

The following categories are used for the frequency of adverse effects: Very common (≥ 1/10), common (≥ 1/100, < 1/10), occasional (≥ 1/1.000, < 1/100), rare (≥ 1/10.000, < 1/1.000), very rare (< 1/10.000), not known (frequency cannot be estimated on the basis of the available data).

Immune system disorders - Not known: Hypersensitivity reactions, Anaphylactic reactions Respiratory, thoracic and mediastinal disorders– Very rare: Laryngospasm Gastrointestinal disorders - Rare: Mouthburn and mouth dryness,

Numbness in the mouth and throat (This effect is part of the drug and disappears after a short time.), Nausea, vomiting

Skin and subcutaneous tissue disorders– Uncommon: Photosensitivity– Very rare: Angioedema

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

In the case of inappropriate use (i.e. when Benzydamine Hydrochloride 0.30 % w/v Oromucosal Spray is swallowed in large amounts), adverse effects such as sleep disorders, restlessness, optical hallucinations (eye flashes, seeing colors and snowflakes), urticaria, exanthemes may occur, photosensitization can not be completely excluded. These phenomena are generally fully reversible.

Symptoms and actions during overdose: Accidental swallowing of small quantities is safe. If very large amounts of Benzydamine Hydrochloride 0.30 % w/v Oromucosal Spray are swallowed by mistaken (e.g., by children), the following symptoms may occur: Vomiting, abdominal pain, restlessness, anxiety, convulsions, ataxia, fever, tachycardia and possibly paralysis. When such symptoms occur, symptomatic treatment is recommended (e.g., respiratory help, removal of poison by gastric lavage, etc.)

Intoxication is only to be expected if large amounts of benzydamine (> 300 mg) are ingestedby mistake.

The symptoms of overdosing by intake of benzydamine mainly occur in the gastrointestinal tract and the central nervous system. The most common gastrointestinal complaints are nausea, vomiting, abdominal pain and esophageal irritation. The symptoms of the central nervous system include dizziness, hallucinations, restlessness, anxiety, and irritability.

In case of an acute overdose, only symptomatic treatment is possible. Patients should be closely monitored and receive supportive treatment. Ensure sufficient liquid supply.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other substances for local, oral treatment ATC code (UK): M01AX07

ATC code (IE): R02AX03

Benzydamine hydrochloride is an indole non-steroidal anti-inflammatory drug (NSAID) for local treatment as an oral spray. Benzydamine hydrochloride is lipophilic at pH 7.2, shows membrane affinity and acts as a membrane-stabilizing agent with local anesthetic effects. In contrast to other NSAIDs, benzydamine hydrochloride does

not inhibit either the cyclo- or lipoxigenase (10-4 mol/l) and is not ulcerogenic. Both phospholipase A2 and lysophosphatide acyltransferase are slightly inhibited (> 10-4 mol/I). The PGE2 synthesis in macrophages is stimulated at 10-4 mol / l. In the concentration range of 10-5 to 10-4 mol / l, the formation of reactive oxygen species from phagocytes is clearly inhibited. Phagocyte degranulation and aggregation are inhibited at 10-4 mol / l. The strongest in vitro effects occur in the inhibition of leukocyte adhesion to the vascular endothelium (3-4 times 10-6 mol/I). Benzydamine hydrochloride has antithrombotic properties in the rat (ED35 8,5 mg/kg p.o.) and reduces the platelet-activating factor (PAF)-induced mortality in mouse (50 mg/kg p.o.; $p < 0,05$). It is concluded that benzydamine hydrochloride acts antiphlogistically by preventing vascular lesions by activated, adherent, and emigrating leukocytes, i.e. Vasoprotective.

The pronounced local anesthetic effect contributes to rapid pain relief. Benzydamine hydrochloride inhibits the permeability of the capillary and thus acts as an anti-edematous agent. These properties are supplemented by the antiseptic effect.

Benzydamine hydrochloride is well tolerated and results in a targeted local treatment of the symptoms of inflammation and dysphagia without causing any significant systemic effects.

5.2 Pharmacokinetic properties

Absorption

In the case of local application, a very good penetration of the active substance through skin and mucous membrane surfaces and an accumulation in the underlying inflammatory changed tissue takes place.

Distribution

When administered orally, benzydamine is distributed fully and slowly into the tissues (distribution volume = 100 l). The binding to plasma proteins is only 10 to 15%.

Biotransformation

In 24 hours, approximately 40% of a single dose is excreted in the form of polar metabolites (mainly benzydamine N-oxide and 5-hydroxybenzydamine glucuronide) and 5% unchanged benzydamine with the urine. 70% of the administered dose are excreted through the kidneys.

Elimination

The plasma half-life is about 10 hours.

5.3 Preclinical safety data

Non-Clinical Data reveal no special hazards for humans based on conventional studies of safety pharmacology, repeated toxicity, genotoxicity, cardiogenic potential, and toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol

Polysorbate 80

Saccharin sodium (E954)

Ethanol 96%

Methyl Parahydroxybenzoate (E 218)

Spearmint flavour (containing benzyl alcohol).

Sodium Hydrogen Carbonate and/or Hydrochloric Acid for pH adjustment

Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

After first opening of the medicinal product: 6 months.

6.4 Special precautions for storage

This medical product does not require any special storage condition. Do not freeze.

6.5 Nature and contents of container

Amber glass bottle (type III) fitted with metered dose pump.

Pack size: 15ml

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Abdi Farma, Unip. Lda.

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2770-071 Paço de Arcos, Portugal

8 MARKETING AUTHORISATION NUMBER(S)

PL 39360/0025

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17/05/2019

10 DATE OF REVISION OF THE TEXT

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