Professional Information

SCHEDULING STATUS

S1

1 NAME OF THE MEDICINE

ANDOLEX ANALGESIC SPRAY, 0,3 % w/v, oromucosal spray, solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 mℓ solution contains

Active ingredient: benzydamine hydrochloride 0,045 g (equivalent to g 0,0402 g benzydamine).

Preservative: Methyl p-hydroxybenzoate 0,1 % w/v.

Contains alcohol 8 % v/v. Excipients with known effect: Polyoxyethylene (40) hydrogenated castor oil.

Contains sugar: glycerol 0,75 g/15 ml.

Contains sweetener, saccharin sodium 0,01 g/15 ml.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oromucosal spray, solution.

4 CLINICAL INFORMATION

4.1 Therapeutic indications

Symptomatic treatment for irritative-inflammatory states, also associated with oropharyngeal pain (e.g. pharyngitis, gingivitis, stomatitis), and after conservative or extractive dental therapy.

4.2 Posology and method of administration

Adults: 2 to 4 sprays directly onto the sore/inflamed area and swallow gently 2 to 6 times a day as necessary (every spray is equivalent to 0,17 ml of solution).

Do not exceed the prescribed dose.

Paediatric population

The safety and efficacy of ANDOLEX ANALGESIC SPRAY in children below 18 years has not yet been established.

4.3 CONTRAINDICATIONS

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

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

The use of the product, especially when prolonged, may cause sensitivity. The patient should be advised to interrupt treatment and to consult their doctor in order to establish suitable therapy.

In a limited number of patients, oro-pharyngeal ulcers may be a sign of more serious pathologies.

If symptoms should persist for more than 3 days, therefore, the patient must consult their doctor.

The use of benzydamine is inadvisable in cases of hypersensitivity to acetylsalicylic acid or other NSAIDs.

ANDOLEX ANALGESIC SPRAY oromucosal spray should be used with caution in patients with history of bronchial asthma, as bronchospasm events may develop in these patients.

ANDOLEX ANALGESIC SPRAY contains methyl p-hydroxybenzoate, which can cause allergic reactions (also delayed).

4.5 Interaction with other medicinal products and other forms of interaction

No human studies on interaction have been performed.

4.6 Fertility, pregnancy and lactation

The safety of ANDOLEX ANALGESIC SPRAY in pregnancy and lactation has not been established. ANDOLEX ANALGESIC SPRAY should not be used during pregnancy and

lactation.

Pregnancy

There is no data regarding the use of benzydamine during pregnancy and

lactation.

Breastfeeding

No studies have been carried out regarding the excretion of the product in

breast milk.

Studies conducted on animals for evaluating effects on pregnancy and during lactation are insufficient (see section 5.3).

Fertility

No data available.

4.7 Effects on ability to drive and use machines

ANDOLEX ANALGESIC SPRAY has no influence on the ability to drive and use machines.

4.8 Undesirable effects

a. Summary of the safety profile

Serious adverse events were not expected and did not occur during the studies performed with topical oromucosal benzydamine.

b. Tabulated list of adverse reactions

The table below shows the undesirable effects, classified according to the MedDRA system organ class. The undesirable effects have been categorised using the following frequency rates: very common (≥1/10); common (≥1/100, < 1/10); uncommon (≥1/1000, <1/100); rare ≥1/10,000, <1/1000); very rare (<1/10,000); unknown (the frequency cannot be established based on the available data).

System organ class	*Frequency: undesirable effects*
Immune-system disorders	*Rare:* hypersensitivity reaction *Unknown*: anaphylactic reactions
Respiratory, thoracic and mediastinal disorders	*Very rare:* laryngospasm
Gastrointestinal disorders	*Rare:* burning sensation and dry mouth.
Skin and subcutaneous tissue disorders	*Uncommon:* photosensitivity *Very rare:* angioedema

c. Paediatric population

Frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

Adverse reactions from clinical trials

The most common adverse effect observed with benzydamine spray, in the treatment of postoperative sore throat due to endotracheal tube cuff, were dry mouth, nausea, cough and vomiting (Huang 2010). Similar results were observed in patients treated with placebo. Local stinging or numbness of the throat and mouth, hoarseness, burning sensation and throat irritations were also reported (Chang 2015, Huang 2010, Kati 2004).

In all other clinical studies considered, no adverse events occurred.

Adverse reactions from spontaneous reporting

The following side effects were spontaneously reported (frequency unknown):

Immune system disorders

Anaphylactic shock, anaphylactic reaction.

Psychiatric disorders

Stress, fear, anxiety.

Nervous system disorders

Loss of consciousness, dizziness.

Eye disorders

Eye swelling.

Ear and labyrinth disorders

Hearing impairment.

Cardiac disorders

Cardio-respiratory arrest, cyanosis, palpitations.

Respiratory, thoracic and mediastinal disorders

Stridor, anoxia, asphyxia, asthma, throat tightness, laryngeal oedema, pharyngeal oedema, dyspnoea.

Gastrointestinal disorders

Mouth, lip and tongue swelling, upper abdominal pain, salivary hypersecretion, oral paraesthesia, tongue oedema, dysphagia, nausea, oral hypoaesthesia.

Skin and subcutaneous tissue disorders

Skin reactions, photosensitivity reactions, macular rash, erythema, rash, pruritus.

Musculoskeletal, connective tissue and bone disorders

Muscular weakness.

Pregnancy, puerperium and perinatal conditions

Early abortion.

Congenital and familial/genetic disorders

Ductus arteriosus premature closure.

General disorders and administrative site conditions

Abasia, brain death, chest pain, foreign body sensation, chest discomfort, pain.

Investigations

Decreased blood pressure.

Injury and poisoning

Foetal exposure during pregnancy.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Intoxication is only expected in case of accidental ingestion of large quantities of benzydamine (> 300 mg).

Symptoms associated with overdose of ingested benzydamine are mainly gastrointestinal symptoms and symptoms of the central nervous system. Most frequent gastrointestinal symptoms are nausea, vomiting, abdominal pain and esophageal irritation. Symptoms of the central nervous system include dizziness, hallucinations, agitation, anxiety and irritability.

Very rarely, in children, excitation, convulsions, sweating, ataxia, tremors and vomiting have been reported after the oral administration of benzydamine dosages about 100 times higher than those of 3 mg lozenges.

There is no specific antidote for benzydamine. In the event of acute overdose, symptomatic and supportive treatment should be provided. Patients should be kept under close observation. Adequate hydration must be maintained.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Category and class: A.16.5 Ear, nose and throat preparations: Other.

Pharmacotherapeutic group: Stomatologic drugs: other agents for local oral treatment.

ATC code: A01AD02

Benzydamine exerts a local anti-inflammatory and analgesic action by stabilizing the cell membrane and inhibiting prostaglandin synthesis. Clinical studies demonstrate that benzydamine is effective for treatment of local mouth and pharynx irritative processes. Moreover, benzydamine has a locally anesthetic effect of a moderate intensity.

5.2 Pharmacokinetic Properties

Absorption

Absorption through the oropharyngeal mucosa is demonstrated by the presence of measurable quantities of benzydamine in human plasma. These levels are insufficient to produce systemic effects.

Distribution

When applied locally, benzydamine has been shown to accumulate in inflamed tissues where it reaches effective concentrations because of its capacity to penetrate the epithelial lining.

Biotransformation

Metabolism is mainly through oxidation dealkylation and conjugation.

Elimination

Excretion occurs mainly in the urine and mostly in the form of inactive metabolites or conjugation products.

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Glycerol
- Ethanol 96 %
- Sodium saccharin
- Methyl p-hydroxybenzoate
- Mint flavor

- Polyoxyethylene (40) hydrogenated castor oils
- Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years at or below 30 °C.

6.4 Special precautions for storage

Protect from light.

6.5 Nature and contents of container

15 ml polyethylene spray bottle.

6.6 Special precautions for disposal and handling

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

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road

Bedfordview

2007

8 REGISTRATION NUMBER

51/16.5/0924

9 DATE OF REVISION OF THE TEXT

March 2022