Professional Information

SCHEDULING STATUS

S1

1 NAME OF THE MEDICINE

ANDOLEX ANALGESIC LOZENGES, benzydamine hydrochloride 3,00 mg per lozenge.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains: Benzydamine HCl 3,00 mg.

Contains sugar: isomalt 2,59 g per lozenge.

Contains sweetener: saccharin sodium 0,65 mg per lozenge.

3 PHARMACEUTICAL FORM

Round green anise-mint flavoured lozenge. With prolonged storage the lozenge may become slightly cloudy and rough.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

Symptomatic relief of painful conditions of the mouth and throat.

4.2 Posology and method of administration

ANDOLEX ANALGESIC LOZENGES should be slowly dissolved in the mouth. One lozenge should be sucked slowly every one to two hours as required up to a maximum of 12 lozenges per day. Uninterrupted treatment should not exceed seven days except under medical supervision.

4.3 Contraindications

Patients with known hypersensitivity to benzydamine hydrochloride or any of the excipients.

4.4 Special warnings and precautions for use

If a sore throat is caused or complicated by a bacterial infection, appropriate antibacterial therapy should be considered.

Excess consumption of products containing isomalt may have a laxative effect.

ANDOLEX ANALGESIC LOZENGES are not recommended in children under 6 years of age.

Benzydamine use is not advisable in patient with hypersensitivity to salicylic acid or other NSAIDs.

Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

The safety of benzydamine hydrochloride has not been established in pregnancy and lactation.

4.7 Effects on ability to drive and use machines

ANDOLEX ANALGESIC LOZENGES has no or negligible influence on the ability to drive and use machines when it is used at the recommended dose.

4.8 Undesirable effects

The most commonly reported reaction is oral numbness. Burning or stinging sensation has been reported. Other local adverse effects include dryness or thirst, tingling, warm feeling in mouth and altered sense of taste.

The following rate values have been used: Very common (≥ 1/10), Common (≥ 1/100 to <1/10), Uncommon (≥ 1/1,000 to < 1/100), Rare (≥ 1/10,000 to < 1/1,000) and Very rare (< 1/10,000), not known (cannot be estimated from the available data).

Immune system disorders

Not known: Anaphylactic reaction, hypersensitivity reaction.

Respiratory, thoracic and mediastinal disorders

Very rare: Laryngospasm.

Gastrointestinal disorders

Rare: Burning mouth, dry mouth.

Not Known: Hypoaesthesia oral

Skin and subcutaneous tissue disorders

Uncommon: Photosensitivity.

Very rare: Angioedema.

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.

Alternately you can contact iNova Pharmaceuticals (Pty) Ltd at

+27 (0) 11 087 0000.

4.9 Overdose

See section 4.8. Adverse central nervous system effects have been reported following over dosage with high doses of benzydamine hydrochloride in solution form. Nausea and vomiting may also occur. Excessive consumption of products containing isomalt may have a laxative effect.

Management

In the event of acute overdosage only symptomatic treatment is possible; the stomach should be emptied by inducing vomiting or by gastric lavage, and the patient carefully observed and given supportive treatment. Adequate hydration must be maintained.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A.16 Ear, nose and throat preparations.

Benzydamine exerts a local ANALGESIC and analgesic action by stabilising the cell membrane and inhibiting prostaglandin synthesis.

Benzydamine possesses a moderate local anaesthetic effect.

5.2 Pharmacokinetic properties

Absorption

The absorption through the mucosa of the mouth and pharynx was demonstrated by the presence of measurable quantities of benzydamine in the human plasma.

Distribution

About 2 hours after the 3 mg lozenge administration, benzydamine peak plasma values of 37.8 ng/ml with an AUC of 367 ng/ml*h were observed. However, these levels are not sufficient to produce pharmacological systemic effects.

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Aromatic 52.503T
- patent blue (E131)
- quinoline yellow (E104)
- saccharin sodium
- isomalt type M.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at or below 30 ºC in a dry place. Protect from light.

KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container

Blisters containing 12 lozenges with 2 blisters (24 lozenges) in a cardboard carton.

6.6 Special precautions for disposal

No special precautions.

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road

Bedfordview

South Africa

8 REGISTRATION NUMBER

31/16/0239.

9 DATE OF FIRST AUTHORISATION

18 March 1997.

10 DATE OF REVISION OF THE TEST

10 December 2020.