Professional Information

SCHEDULING STATUS

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1 NAME OF MEDICINE

ANDOLEX–C LOZENGES ORANGE,

benzydamine hydrochloride 3,00 mg and

cetylpyridinium chloride 1,33mg per lozenge.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains:

Benzydamine HCl 3,00 mg

Cetylpyridinium chloride 1,33 mg

Contains sugar: isomalt 2,58 g

Contains sweetener: Sucralose 0,65 mg

3 PHARMACEUTICAL FORM

Round, orange lozenges with a sweet orange flavour

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic relief of minor infections and painful conditions of the mouth and throat.

4.2 Posology and method of administration

Andolex-C Lozenges Orange should not be chewed. They 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.

4.3 Contraindications

Patients with known hypersensitivity to benzydamine, cetylpyridinium chloride, 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-C Lozenges Orange 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. Caution should be exercised in these patients.

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-C Lozenges Orange 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

Symptoms

See Section 4.8. Adverse central nervous system effects have been reported following overdosage with high doses of benzydamine hydrochloride in solution form. Nausea and vomiting may also occur. Excess 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.16.4 Naso-pharyngeal and bucco-pharyngeal antiseptics.

ATC code: R02AX03 – other throat preparations.

Cetylpyridinium chloride is a quaternary pyridinium antiseptic with bactericidal and fungicidal activity.

Benzydamine hydrochloride has local analgesic and anti-inflammatory properties.

Benzydamine hydrochloride possesses a moderate local anaesthetic effect.

5.2 Pharmacokinetic properties

Benzydamine hydrochloride

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

- Citric acid
- isomalt
- levomenthol
- orange flavour
- polysorbate
- sucralose
- sunset yellow (CI 15985).

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 30 °C.

Protect from light.

KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container

Blister packs containing 2, 4, 6, 8, and 16 lozenges.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road, Bedfordview,

South Africa.

8 REGISTRATION NUMBER

36/16.4/0195

DATE OF FIRST AUTHORISTION

7 March 2003.

10 DATE OF REVISION OF TEXT

20 November 2020.

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