Professional Information

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

ANDOLEX-C ORAL GEL,

benzydamine hydrochloride 10,0 mg/g and

cetylpyridinium chloride 1,0 mg/g, gel. (Gel)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of ANDOLEX-C ORAL GEL contains:

Benzydamine Hydrochloride 10,0 mg

Cetylpyridinium Chloride 1,0 mg

Contains sweetener: Saccharin sodium 0,01 g/10 g.

SUGAR FREE

3 PHARMACEUTICAL FORM

Clear, colourless, peppermint flavoured gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

Temporarily relieves painful inflamed conditions of the mouth, including mouth and denture ulcers and sore gums

4.2 Posology and method of administration

1. Apply approximately 1 cm of gel with finger.
2. Gently massage into sore area.
3. Do not eat or drink for 15 minutes.
4. Apply every 2 to 3 hours up to a maximum of 12 times per day. If symptoms persist, see your doctor or dentist.

4.3 Contraindications

Patients with known hypersensitivity to benzydamine or cetylpyridinium chloride.

ANDOLEX-C ORAL GEL is not recommended in children under 6 years of age.

Refer to Section 4.6.

4.4 Special warnings and precautions for use

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

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 ORAL GEL has no or negligible influence on the ability to drive and use machines.

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. Hypersensitivity reactions occur rarely but may include urticarial, photosensitivity, and bronchospasm. Serious allergic reaction (anaphylactic shock), signs of which may include difficulty breathing, chest pain or chest tightness, and/or feeling dizzy/faint, severe itching of the skin or raised lumps on the skin, swelling of the face, lips, tongue and/or throat, and which may be potentially life-threatening.

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 and section 4.4. 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. There is no specific antidote for benzydamine and treatment should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacocynamic properties

A 16.4 Naso-pharyngeal and bucco-pharyngeal antiseptics

Benzydamine hydrochloride has local analgesic and anti-inflammatory properties.

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Glycerol
- natrosol 250 HHX Pharm
- peppermint oil crystal 2110
- polysorbate 20
- purified water
- saccharin sodium.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at or below 30 °C

KEEP OUT OF REACH OF CHILDREN

Keep well closed.

6.5 Nature and contents of container

White aluminium laminated tubes containing 10 g.

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

33/16.4/0285.

9 DATE OF FIRST AUTHORISATION

26 April 2002

10 DATE OF REVISION OF TEXT

24 November 2020