PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

1 NAME OF MEDICINE

Andolex, benzydamine hydrochloride 22,5 mg/15 ml solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 ml contains

benzydamine hydrochloride	22.5 mg
Preservative:	
methyl hydroxybenzoate	0.1 % m/v

Contains alcohol 10 % v/v

SUGAR FREE.

3 PHARMACEUTICAL FORM

A pleasant tasting, clear, green solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

Symptomatic relief of painful inflammatory conditions of the mouth and throat including:

Traumatic conditions: Pharyngitis following tonsillectomy or after the use of nasogastric tube

Inflammatory conditions: Pharyngitis, aphthous ulcers and oral ulceration due to radiation therapy

Dentistry: For use after dental operations.

4.2 Posology and method of administration

Oral Rinse: Rinse or gargle with 15 ml (approximately one tablespoonful) every 1½ to 3 hours as required for pain relief. The solution should be expelled from the mouth after use.

Spray: 5 to 10 sprays directly onto the painful or inflamed area and swallow gently. Repeat every 1½ to 3 hours as necessary.

Andolex should generally be used undiluted, but if “stinging” occurs, the rinse may be diluted with water.

Avoid contact with the eyes.

Elderly: No special usage recommendations are made for elderly patients.

4.3 Contraindications

Sensitivity to benzydamine hydrochloride or to any of the components of this Andolex (see section 6.1).

Andolex is not recommended in children under the age of 12 years.

4.4 Special warnings and precautions for use

Do not swallow. If a stinging or burning sensation occurs, Andolex may be diluted with water. Avoid contact with the eyes.

Uninterrupted treatment should not exceed 7 days, except under medical supervision.

Andolex contains methyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

Effects on ability to drive and use machines:

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

4.5 Interaction with other medicines and other forms of interaction

See section 4.3 and section 4.4.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

Andolex has no or negligible effect on the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders

Less frequent: Hypersensitivity reactions including urticaria, rash, laryngospasm, photodermatitis.

Frequency unknown:

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.

Nervous system disorders

Less frequent: Light-headedness.

Gastrointestinal disorders

Frequency unknown: Nausea and vomiting

General disorders and administrative site conditions

Less frequent: Oral tissue numbness and stinging or burning sensation, disturbance of taste.

4.9 Overdose

See section 4.8.

There is no specific antidote for benzydamine and should excessive quantities be ingested, the treatment should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A.16 Ear, nose and throat preparations

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

5.2 Pharmacokinetic properties

When administered as a local application benzydamine has a low systemic absorption which reduces the potential of systemic side effects. Metabolism is mainly through oxidation, dealkylation and conjugation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Glycerol
- saccharin sodium
- mouthwash flavour

- polysorbate
- quinoline yellow
- patent blue
- purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C. Protect from light. Do not leave the uncartoned bottle in direct sunlight.

KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container

Oral Rinse: Bottles containing 200 ml and 2,5 L

Spray: Bottles containing 30 ml

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

Z/16/40

9 DATE OF FIRST AUTHORISATION

Date of registration: May 1994

10 DATE OF REVISTION OF THE TEXT

15 January 2021.