220 mm

PRINT FREE AREA FOR GLUING

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Scheduling status S1

Proprietary name and dosage form

Andolex-C

ORAL GEL (Gel)

PEEL HERE TO REVEAL PRODUCT INFORMATION

COMPOSITION
Each 1 g contains:
Benzydamine hydrochloride 10,0 mg
Cetylpyridinium chloride 1,0 mg
Other ingredients are glycerol, natrosol 250 HHX pharma, peppermint oil crystal 2110, polysorbate 20, purified water and sodium saccharin. SUGAR FREE.

PHARMACOLOGICAL CLASSIFICATION
A 16.4 Naso-pharyngeal and bucco-pharyngeal antiseptics.

PHARMACOLOGICAL ACTION
Benzydamine hydrochloride has local analgesic and anti-inflammatory properties.
Cetylpyridinium chloride is a quarternary pyridinium antiseptic with bactericidal and fungicidal activity.

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

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 **PREGNANCY AND LACTATION**

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

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

DOSAGE AND DIRECTIONS FOR USE
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/day.

If symptoms persist, see your doctor or dentist.

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

Immune System Disorders
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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
See **SIDE EFFECTS** and **WARNINGS AND SPECIAL PRECAUTIONS.** 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.

IDENTIFICATION.
Clear, colourless, peppermint flavoured gel.

PRESENTATION
White aluminium laminated tubes containing 10 g.

STORAGE INSTRUCTIONS
Store at or below 30 °C.
KEEP OUT OF REACH OF CHILDREN
Keep well closed.

REGISTRATION NUMBER
33/16.4/0285

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
iNova Pharmaceuticals (Pty) Ltd
15e Riley Road, Bedfordview 2007

DATE OF PUBLICATION OF THE PACKAGE INSERT
26 April 2002

BOTSWANA
Scheduling Status: 3
Pharmacological classification: ATC: A01A D02 Stomatological preparations: other agents for local oral treatment
Licence Number: BOT 0200516

NAMIBIA
Scheduling Status: NS1
Registration Number: 06/16.4/0095

inova pharmaceuticals
LT015503
LT049.08.17

140 mm

Skeduleringstatus S1

Eiendomsnaam en doseervorm

Andolex-C

ORAL GEL (Gel)

SAMESTELLING
Elke 1 g bevat:
Bensidamienhidrochloried 10,0 mg
Setielpiridiniumchloried 1,0 mg
Ander onaktiewe bestanddele sluit in gliserol, natrosol 250 HHX pharma, pepermentolie kristalle 2110, polisorbaat 20, gesuiwerde water and natriumsakkarien.
SUIKER VRY.

FARMAKOLOGIESE KLASSIFIKASIE
A 16.4 Neus-antiseptika en mond-en-keelantiseptika.

FARMAKOLOGIESE WERKING
Bensidamienhidrochloried het plaaslike analgetiese en anti-inflammatoriese eienskappe.
Setielpiridiniumchloried is 'n kwaternêre antiseptikum met kiemdodende en swamdodende aktiwiteit.

INDIKASIES
Tydelike verligting van pynlike geïnflammeerde kondisies van die mond, insluitende mond en kunstand ulserasies en seer tandvleise.

KONTRA-INDIKASIES
Pasiënte met bekende hipersensitiwiteit vir bensidamienhidrochloried of setielpiridiniumchloried.
ANDOLEX-C ORAL GEL word nie aanbeveel vir kinders jonger as 6 jaar oud nie.
Verwys na **SWANGESKAP EN LAKTASIE**.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Indien 'n seer mond veroorsaak is of gekompliseer word deur 'n bakteriële infeksie, moet toepaslike antibakteriële terapie oorweeg word.

SWANGERSKAP EN LAKTASIE
Die veiligheid van bensidamienhidrochloried is nog nie vasgestel in swangerskap en laktasie nie.

DOSIS EN GEBRUIKSAANWYSINGS
1. Wend ongeveer 1 cm gel met die vinger aan.
2. Masseer sagkuns in die seer area in.
3. Moet nie eet of drink vir 15 minute nie.
4. Wend elke 2 tot 3 ure aan tot ‘n maksimum van 12 keer/dag.

Indien simptome volhou, raadpleeg u dokter of tandarts.

NEWE-EFFEKTE
Die mees algemene reaksie is 'n dooierige gevoel in die mond. 'n Branderige- of prikkelsensasie is al aangemeld. Ander plaaslike newe-effekte sluit in droogheid van die mond of dors, prikkeling, 'n warm gevoel in die mond en 'n veranderde sin van smaak.

Immuunsisteem Versteurings
Frekwensie onbekend:
Ernstige allergiese reaksie (anafilaktiese skok), tekens sluit moeilike asemhaling, borspyn of bors wat toetrek, en / of duiseligheid/flou gevoel, erge jeuk van die vel of opghewe knoppe op die vel, swelling van die gesig, lippe, tong en / of keel in, en kan potensieel lewensgevaarlik wees.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Sien **NEWE-EFFEKTE** en **WAARSKUWINGS en SPESIALE VOORSORGMAATREËLS.** Newe-effekte van die sentrale senuweestelsel is vermeld met oordosering van bensidamienhidrochloried in oplossing. Naarheid en braking kan voorkom. Daar is geen spesifieke teenmiddel vir bensidamienhidrochloried nie, en behandeling behoort simptomaties en ondersteunend te wees.

IDENTIFIKASIE
Helder, kleurlose, pepperment gegeurde gel.

AANBIEDING
Wit aluminium gelamineerde buise wat 10 g bevat.

BERGINGSAANWYSINGS
Bewaar teen of benede 30 °C.
HOU BUITE BEREIK VAN KINDERS
Hou dig toe.

REGISTRASIENOMMER
33/16.4/0285

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
iNova Pharmaceuticals (Pty) Ltd.
Rileyweg 15e, Bedfordview 2007

DATUM VAN PUBLIKASIE VAN DIE VOUBILJET
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