PACKAGE INSERT

Andolex®

SCHEDULING STATUS
S1
PROPRIETARY NAME AND DOSAGE FORM
ANDOLEX solution
COMPOSITION
Each 15 mℓ contains benzydamine hydrochloride 22,5 mg
Preservative: methyl hydroxybenzoate 0,1 % *m/v*
Contains alcohol 10 % *v/v*
Contains sweetener: Saccharin sodium 4,8 mg/15mℓ
The other excipients are glycerol, mouthwash flavour, polysorbate, quinoline yellow, patent blue and purified water. SUGAR FREE.
PHARMACOLOGICAL CLASSIFICATION
A 16 Ear, nose and throat preparations
PHARMACOLOGICAL ACTION
Pharmacodynamic properties
Benzydamine exerts a local anti-inflammatory and analgesic action by stabilising the cell membrane and inhibiting prostaglandin synthesis.
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.
INDICATIONS
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
CONTRAINDICATIONS
Sensitivity to benzydamine hydrochloride or to any of the components of **ANDOLEX** (see **COMPOSITION**).
ANDOLEX is not recommended in children under the age of 12 years.
WARNINGS AND SPECIAL PRECAUTIONS
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.
INTERACTIONS
See **CONTRAINDICATIONS** and **WARNINGS AND SPECIAL PRECAUTIONS**.
PREGNANCY AND LACTATION
The safety of ANDOLEX in pregnancy and lactation has not been established.
DOSAGE AND DIRECTIONS FOR USE
Oral Rinse:
Rinse or gargle with 15 mℓ (approximately one tablespoon full) 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.
SIDE 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.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
See **SIDE EFFECTS.**
There is no specific antidote for benzydamine and should excessive quantities be ingested, the treatment should be symptomatic and supportive.
IDENTIFICATION
A pleasant tasting, clear, green solution.
PRESENTATION
Oral Rinse: Bottles containing 200 mℓ and 2,5 ℓ
Spray: Bottles containing 30 mℓ
STORAGE INSTRUCTIONS
Store at or below 25 °C. Protect from light.
Do not leave the uncartoned bottle in direct sunlight.
KEEP OUT OF REACH OF CHILDREN
REGISTRATION NUMBER
Z/16/40
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 THIS PACKAGE INSERT
Date of registration: May 1994
Date of latest revision: 25 November 2016
Final Product Manufacturer
Pharma-Q (Pty) Ltd
50 Commando Road, Industria, Johannesburg
Country of Origin
South Africa

BOTSWANA
Scheduling status (**Oral Rinse**): 4
License number: BOT 9700124

BOTSWANA
Scheduling status (**Spray**): 3
License number: BOT 1402675

NAMIBIA
Scheduling status : NS1
Registration number : 04/16/0951

ZIMBABWE
Distribution category: Pharmacist Initiated Medicine (PIM)
Registration number: 20.3.6 Ear, nose, throat and mouth preparations: Others
Registration number: 98/20.3.6/3302

ZAMBIA: General Sale
Marketing Authorization No: Andolex Spray: 478/001L
Andolex Oral Rinse 200 ml: 478/003L

VOUBILJET

Andolex®

SKEDULERINGSTATUS
S1
EIENDOMSNAAM EN DOSEERVORM
ANDOLEX oplossing
SAMESTELLING
Elke 15 mℓ bevat bensidamienhidrochloried 22,5 mg
Preserveermiddel: metielhidroksiebensoaat 0,1 % *m/v*
Bevat alkohol 10 % *v/v*
Bevat versoeter: Natriumsakkarien 4,8 mg/15mℓ
Ander bestanddele sluit in gliserol, mondspoelmiddel geur, polisorbaat, kinolien geel, patent blou kleur en gesuiwerde water. SUIKER VRY.
FARMAKOLOGIESE KLASSIFIKASIE
A 16 Oor, neus en keelpreparate
FARMAKOLOGIESE WERKING
Farmakodinamiese eienskappe
Bensidamien het 'n plaaslike anti-inflammatoriese en analgetiese werking deurdat dit die selmembraan stabiliseer en prostaglandien-sintese inhibeer.
Farmakokinetiese eienskappe
Wanneer dit topikaal aangewend word, het bensidamien 'n lae sistemiese absorpsie wat die potensiaal van sistemiese newe-effekte verminder. Metabolisme is hoofsaaklik deur oksidasie, dealkilering en konjugasie.
INDIKASIES
Simptomatiese verligting van pynlike inflammatoriese kondisies van die mond en keel, insluitende:
Traumatiese toestande: Faringitis wat volg na 'n tonsillektomie of na gebruik van 'n nasogastriese buis.
Inflammatoriese toestande: Faringitis, afteuse en orale ulserasies as gevolg van bestralings-terapie.
Tandheelkunde: Vir gebruik na tandheelkundige operasies.
KONTRA-INDIKASIES
Sensitiwiteit teenoor bensidamienhidrochloried of teenoor enige van die bestanddele van **ANDOLEX** (verwys na **SAMESTELLING**).
ANDOLEX word nie aanbeveel vir gebruik in kinders onder 12 jaar oud nie.
WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Moenie sluk nie. As 'n branderige sensasie voorkom, kan **ANDOLEX** verdun word met water. Vermy kontak met die oë.
Ononderbroke behandeling moet nie langer as 7 dae duur nie, behalwe onder mediese toesig.
ANDOLEX bevat metielhidroksiebensoaat wat allergiese reaksies kan veroorsaak (moontlik vertraagde reaksies).
Uitwerking op die vermoë om te bestuur en die gebruik van masjienerie:
ANDOLEX het geen of 'n weglaatbare invloed op die vermoë om te bestuur en om masjienerie te gebruik.
INTERAKSIES
Sien **KONTRA-INDIKASIES** en **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**.
SWANGERSKAP EN LAKTASIE
Die veiligheid van ANDOLEX tydens swangerskap en laktasie is nie vasgestel nie.
DOSIS EN GEBRUIKSAANWYSINGS
Mondspoelmiddel:
Spoel of gorrel met 15 mℓ (ongeveer een eetlepelvol) elke 1½ tot 3 uur soos benodig vir verligting van pyn. Die oplossing moet uitgespoeg word na gebruik.
Sproei:
5 tot 10 sproeie direk op die pynlike of ontsteekte area en sluk dan sagkuns in. Herhaal elke 1½ tot 3 uur soos benodig.
ANDOLEX word in die algemeen onverdun gebruik, maar indien branderigheid voorkom, kan die spoelmiddel met water verdun word. Vermy kontak met die oë.
Bejaardes: Geen spesiale gebruiksaanwysings word aanbeveel nie vir bejaarde pasiënte nie.
NEWE-EFFEKTE
Immuunsisteem versteurings
Minder dikwels: Hipersensitiwiteitsreaksies insluitend urtikarie, uitslag, laringospasma en fotodermatitis.
Frekwensie onbekend: Ernstige allergiese reaksie (anafilaktiese skok), tekens sluit moeilike asemhaling, borspyn of 'n toe bors, 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.
Senuweestelselversteurings
Minder dikwels: Lighoofdigheid.
Gastroïntestinale versteurings
Frekwensie onbekend: Naarheid en braking.
Algemene versteurings en versteurings van die area van toediening
Minder dikwels: Gevoelloosheid van orale weefsel en steek- of branderige sensasie, versteuring van smaak.
BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Sien **NEWE-EFFEKTE**.
Daar is geen spesifieke teenmiddel vir bensidamien nie. Indien oormatige hoeveelhede ingeneem word, is die behandeling simptomaties en ondersteunend.
IDENTIFIKASIE
'n Helder, groen oplossing met 'n aangename smaak.
AANBIEDING
Mondspoelmiddel: Bottels wat 200 mℓ en 2,5 ℓ bevat
Sproei: Bottels wat 30 mℓ bevat
BERGINGSINSTRUKSIES
Bewaar teen of benede 25 °C. Beskerm teen lig.
Moenie die houer sonder die oorspronklike verpakking in direkte sonlig, laat staan nie. **HOU BUITE BEREIK VAN KINDERS**.
REGISTRASIENOMMER
Z/16/40
NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
iNova Pharmaceuticals (Pty) Ltd
Rileyweg 15E, Bedfordview, 2007
DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
Datum van registrasie: Mei 1994
Datum van laaste hersiening: 25 November 2016
Vervaardiger
Pharma-Q (Pty) Ltd
50 Commando Road, Industria, Johannesburg
Oorsprong
Suid-Afrika

PATIENT INFORMATION LEAFLET

Andolex®

SCHEDULING STATUS
S1
PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
ANDOLEX, benzydamine hydrochloride 22,5 mg/15 mℓ solution.
Read all of this leaflet carefully because it contains important information for you.
ANDOLEX is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use **ANDOLEX** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **ANDOLEX** with any other person.
- Ask your pharmacist if you need more information or advice.

You must see a doctor if your symptoms worsen or do not improve after 7 days.
WHAT ANDOLEX CONTAINS
The active substance is benzydamine hydrochloride 22,5 mg/15 mℓ.
The preservative is methyl hydroxybenzoate 0,1 % *m/v*.
ANDOLEX contains alcohol 10 % *v/v*.
Contains sweetener: Saccharin sodium 4,8 mg/15mℓ
The other excipients are glycerol, mouthwash flavour, polysorbate, quinoline yellow, patent blue and purified water. SUGAR FREE.
WHAT ANDOLEX IS USED FOR
ANDOLEX is used for symptomatic relief of painful inflammatory conditions of the mouth and throat including:
Traumatic conditions: Inflammation of the pharynx (pharyngitis) following removal of tonsils or after the use of nasogastric tube.
Inflammatory conditions: Pharyngitis, mouth ulcers and oral ulceration due to radiation therapy
Dentistry: For use after dental operations
BEFORE YOU USE ANDOLEX
Do not use ANDOLEX:
- if you are hypersensitive (allergic) to benzydamine hydrochloride or any of the other ingredients of **ANDOLEX**
- if you are under 12 years old
- if you are pregnant.

Pregnancy and Breastfeeding
Safety in pregnancy and breastfeeding has not been established. If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before using **ANDOLEX**.
Driving and using machinery
ANDOLEX has no or negligible influence on the ability to drive and use machines.
Important information about some of the ingredients of ANDOLEX:
ANDOLEX contains alcohol.
ANDOLEX contains the preservative, methyl hydroxybenzoate, which may cause allergic reactions which can be delayed.
Using other medicines with ANDOLEX:
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
HOW TO USE ANDOLEX
Do not share medicines prescribed for you with any other person.
Oral Rinse:
Rinse or gargle with 15 mℓ (approximately one tablespoon full) every 1½ to 3 hours as required for pain relief. **ANDOLEX** 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.
Elderly: No special usage recommendation are made for elderly patients.
You should check with your doctor or pharmacist if you are unsure how to use **ANDOLEX**.
If you feel that the effect of **ANDOLEX** is too strong or too weak, talk to your doctor or pharmacist.
If you take more ANDOLEX than you should
In the event of overdosing, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
If you forget to use a dose of ANDOLEX
Do not use a double dose to make up for forgotten individual doses. Use the next dose as previously instructed.
POSSIBLE SIDE EFFECTS
ANDOLEX can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult with your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking **ANDOLEX** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- if you experience difficulty breathing, chest pain or chest tightness, feeling dizzy or faint, severe itching of the skin or raised lumps on the skin, swelling of the face, lips, tongue and throat
- if you experience difficulty to speak or breathe (laryngospasm)
- if you experience light sensitivity (photodermatitis)
- if you get a rash or hives (urticaria)

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ANDOLEX**. You may need urgent medical attention or hospitalisation.
Tell your doctor as soon as possible if you notice any of the following:
- nausea and vomiting
- light-headedness
- oral tissue numbness
- stinging or burning sensation
- disturbance of taste.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
STORING AND DISPOSING OF ANDOLEX
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store at or below 25 °C
- Do not use after the expiry date stated on the label
- Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage system (e.g. toilets).
PRESENTATION OF ANDOLEX
Oral Rinse: Bottles containing 200 mℓ and 2,5 ℓ
Spray: Bottles containing 30 mℓ
IDENTIFICATION OF ANDOLEX
A pleasant tasting, clear, green solution.
REGISTRATION NUMBER
Z/16/40
NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER
iNova Pharmaceuticals (Pty) Ltd
15E Riley Road, Bedfordview, 2007
DATE OF PUBLICATION OF THIS PACKAGE INSERT
Date of registration: May 1994
Date of latest revision: 25 November 2016
Final Product Manufacturer
Pharma-Q (Pty) Ltd
50 Commando Road, Industria, Johannesburg
Country of Origin
South Africa

081234
A3893

PASIËNTINLIGTINGSPAMFLET

Andolex®

SKEDULERINGSTATUS
S1
EIENDOMSNAAM, STERKTE EN DOSEERVORM
ANDOLEX, bensidamienhidrochloried 22,5 mg/15 mℓ oplossing.
Lees hierdie hele pamflet noukeurig deur omdat dit belangrike inligting bevat.
ANDOLEX is sonder 'n voorskrif beskikbaar om minder ernstige toestande te behandel. Nogtans moet **ANDOLEX** met omsigtigheid gebruik word om die beste resultate te verkry.
- Hou hierdie pamflet. Dit mag nodig wees dat jy dit weer moet lees.
- Moenie **ANDOLEX** met iemand anders deel nie.
- Vra jou apteker as jy nog inligting of raad nodig het.

Raadpleeg 'n dokter indien jou simptome vererger of nie verbeter binne 7 dae nie.
WAT ANDOLEX BEVAT
Die aktiewe bestanddeel is bensidamienhidrochloried 22,5 mg/15 mℓ.
Die preserveermiddel is metielhidroksiebensoaat 0,1 % *m/v*.
ANDOLEX bevat alkohol 10 % *v/v*.
Bevat versoeter: Natriumsakkarien 4,8 mg/15mℓ
Ander bestanddele sluit in gliserol, mondspoelmiddel geur, polisorbaat, kinolien geel, patent blou kleur en gesuiwerde water. SUIKER VRY.
WAARVOOR ANDOLEX GEBRUIK WORD
ANDOLEX word gebruik vir die simptomatiese verligting van pynlike, inflammatoriese toestande van die mond en keel insluitende die volgende:
Traumatiese kondisies: Inflammasie van die farinks na 'n tonsilektomie (verwydering van die mangels) of na die gebruik van 'n nasogastriese buis.
Inflammatoriese toestande: Faringitis, mondulkusse en orale ulserasies na bestraling.
Tandheelkunde: Vir gebruik na tandheelkundige operasies.
VOORDAT U ANDOLEX GEBRUIK
Moenie ANDOLEX gebruik:
- indien jy hipersensitief (allergies) vir bensidamienhidrochloried of enige van die ander bestanddele van **ANDOLEX** is nie
- indien jy jonger as 12 jaar oud is nie
- indien jy swanger is nie.

Swangerskap en borsvoeding
Die veiligheid tydens swangerskap en borsvoeding is nie bepaal nie. Indien jy swanger is of jou baba borsvoed, moet jy jou dokter, apteker of ander gesondheidskundige raadpleeg vir advies voordat jy **ANDOLEX** gebruik.
Motorbestuur en gebruik van masjinerie
ANDOLEX het geen of 'n weglaatbare effek op die vermoë om te bestuur en om masjiene te gebruik.
Belangrike inligting rakende sommige van die bestanddele in ANDOLEX:
ANDOLEX bevat alkohol.
ANDOLEX bevat die preserveermiddel, metielhidroksiebensoaat, wat allergiese reaksies kan versoorsaak (moontlik vertraagde reaksies).
Gebruik van ander medisyne saam met ANDOLEX
Stel altyd jou gesondheidskundige in kennis as jy enige ander medisyne gebruik.
(Dit sluit komplementêre en tradisionele medisyne in.)
HOE OM ANDOLEX TE GEBRUIK
Moenie medisyne wat vir jou voorgeskryf is aan enigiemand anders gee nie.
Mondspoelmiddel:
Spoel of gorrel met 15 mℓ (ongeveer een eetlepel vol) elke 1½ tot 3 uur soos benodig vir die verligting van pyn. **ANDOLEX** moet uit die mond gespoeg word na gebruik.
Sproei:
Spuit 5 tot 10 sproeie direk op die pynlike of ontsteekte area en sluk sagkuns in. Herhaal elke 1½ tot 3 uurliks soos benodig.
Bejaarde persone:
Geen spesiale gebruiksaanwysings word aanbeveel vir bejaarde pasiënte nie. Bevestig met jou dokter of apteker indien jy onseker is hoe om **ANDOLEX** te gebruik.
Indien jy voel dat effek van **ANDOLEX** te sterk of te flou is, raadpleeg jou dokter of apteker.
As jy meer ANDOLEX gebruik as wat jy moet
Indien oordosering plaasvind, raadpleeg jou dokter of apteker. Indien hulle nie beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Indien jy vergeet om ANDOLEX te gebruik
Moenie 'n dubbel dosis gebruik om vir 'n gemiste dosis op te maak nie. Gebruik die volgende dosis soos voorheen geadviseer.
MOONTLIKE NEWE-EFFEKTE
ANDOLEX kan newe-effekte hê. Nie al die newe-effekte wat vir hierdie medisyne aangemeld is, is in hierdie pamflet opgeneem nie. As jou algemene gesondheidstoestand versleg of as jy newe-effekte ervaar terwyl jy **ANDOLEX** gebruik, moet jy jou dokter, apteker of ander gesondheidskundige vir advies raadpleeg.
Indien enige van die volgende voorkom, staak onmiddellik die gebruik van **ANDOLEX** en stel jou dokter dadelik in kennis of gaan na die naaste ongevalle departement by jou naaste hospitaal:
- indien jy sukkel om asem te haal, borspyn of 'n toe bors, duiseligheid of flou gevoel erge jeuk of opgehewe knoppe op die vel, swelling van die gesig, lippe, tong en keel ondervind
- indien jy sukkel om te praat of asem te haal (laringospasma)
- indien jy sensitief is vir lig (fotodermatitis)
- indien jy 'n uitslag of galbulte kry (urtikarie)

Bogenoemde is almal baie ernstige newe-effekte. Indien jy hulle ervaar, kon jy dalk 'n ernstige allergiese reaksie teenoor **ANDOLEX** gehad het. Jy mag ernstige mediese aandag of hospitalisasie benodig.
Stel jou dokter so gou moontlik in kennis indien jy een van die volgende opmerk:
- naarheid en braking
- lighoofdigheid
- gevoelloosheid van mondweefsel
- steek of branderige sensasie
- versteuring van smaak.

Stel jou dokter of apteker in kennis indien jy enige newe-effekte opmerk wat nie in hierdie pamflet beskryf word nie.
BERGING EN WEGDOENING VAN ANDOLEX
BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Bewaar teen of benede 25 °C
- Moenie na die vervaldatum op die etiket gebruik nie
- Gee alle ongebruikte medisyne terug aan jou apteker.

Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.
AANBIEDING VAN ANDOLEX
Mondspoelmiddel: Bottels wat 200 mℓ en 2,5 ℓ bevat
Sproei: Bottels wat 30 mℓ bevat
IDENTIFIKASIE VAN ANDOLEX
'n Helder, groen oplossing met 'n aangename smaak.
REGISTRASIENOMMER
Z/16/40
NAAM EN ADRES VAN DIE HOUER VAN REGISTRASIE
iNova Pharmaceuticals (Pty) Ltd
Rileyweg 15E, Bedfordview, 2007
DATUM VAN PUBLIKASIE
Datum van registrasie: Mei 1994
Datum van laaste hersiening: 25 November 2016
081234 A3893

Pro-Print