Andolex®-C
Oral Rinse

SCHEDULING STATUS
S1
PROPRIETARY NAME AND DOSAGE FORM
ANDOLEX-C ORAL RINSE
COMPOSITION

Each 15 mℓ contains benzydamine hydrochloride	22,5 mg
Chlorhexidine gluconate	18 mg
Contains alcohol	9 % *v/v*

Contains sugar: Sorbitol solution 3,75 g/15 mℓ
Other ingredients include polyoxyl 40 hydrogenated castor oil, peppermint oil, aniseed, carmoisine and purified water.
PHARMACOLOGICAL CLASSIFICATION
A 16.4 Nasopharyngeal and bucco-pharyngeal antiseptics
PHARMACOLOGICAL ACTION
Pharmacodynamic properties
Benzydamine hydrochloride has local analgesic and anti-inflammatory properties by stabilising the cellular membrane and inhibiting prostaglandin synthesis.
Chlorhexidine has antiseptic and disinfectant properties.
Pharmacokinetic properties
Benzydamine:
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.
Chlorhexidine:
Minimal systemic absorption is observed. Chlorhexidine is poorly absorbed from the gastrointestinal tract and skin.
INDICATIONS
For the relief of minor infections and painful inflammatory conditions of the mouth and throat.
Chlorhexidine in **ANDOLEX-C ORAL RINSE** helps to reduce the development of plaque.
CONTRAINDICATIONS
Patients with known hypersensitivity to benzydamine, chlorhexidine or to any of the other ingredients of the formulation (see **COMPOSITION**).
ANDOLEX-C ORAL RINSE is not recommended in children under 6 years of age.
WARNINGS AND SPECIAL PRECAUTIONS
Do not swallow. If a burning or stinging sensation occurs, **ANDOLEX-C ORAL RINSE** can be diluted with water. Avoid contact with the eyes. Should it come in contact with the eyes, wash out thoroughly with water. Uninterrupted treatment should not exceed 7 days except under medical supervision.
Patients with the rare hereditary condition of sorbitol intolerance should not use ANDOLEX-C ORAL RINSE.
Contains sorbitol which may have an effect on blood sugar levels in patients with Diabetes Mellitus.
Effects on ability to drive and use machines
ANDOLEX-C ORAL RINSE has no or negligible influence on the ability to drive and use machines.
INTERACTIONS
Anionic agents in some toothpastes are incompatible with chlorhexidine. In order that the antiplaque effect of chlorhexidine is not reduced, it has been recommended that at least 30 minutes should be allowed to elapse between teeth brushing and rinsing with **ANDOLEX-C ORAL RINSE**.
PREGNANCY AND LACTATION
The safety of ANDOLEX-C ORAL RINSE in pregnancy and lactation has not been established.
DOSAGE AND DIRECTIONS FOR USE
Adults
Gargle:
Gargle with 15 mℓ (approximately one tablespoon) for at least 30 seconds at 1½ to 3 hourly intervals, as needed. The solution should be expelled from the mouth after use and not swallowed.
Rinse for oral lesions:
15 mℓ (approximately one tablespoon) which should be held in the mouth and swirled around for at least 30 seconds, with repeat use every 1½ to 3 hours throughout the day, as needed. 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-C ORAL RINSE should generally be used undiluted, but if stinging occurs, the rinse may be diluted with water.
Children (6 to 12 years)
Use 5 to 15 mℓ as a gargle if able to do so, or as an oral rinse, every 3 hours.
Avoid contact with the eyes.

How to clean and care for ANDOLEX-C spray:
Rinse the actuator spindle and nozzle after every use to avoid sporadic blockages of the spray tube. Rinse the spray tube in warm, running water for at least 30 seconds and let the water run through the spray tube. This is very important as sometimes the small opening where the medicine comes out can become blocked. Shake off the excess water and leave the spray tube to dry completely.
Note: Blockage from medication build-up is more likely to occur if the spray tube is not allowed to dry thoroughly. The spray should be stored in an upright position.

SIDE EFFECTS
Immune system disorders
Less frequent: Hypersensitivity reactions including urticaria, rash, bronchospasm or laryngospasm and 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.
Gastrointestinal disorders
Frequency unknown: Gastro-intestinal disturbances
General disorders and administrative site conditions
Less frequent: Oral tissue numbness and stinging sensation, dryness or thirst, reversible discolouration of the tongue and teeth, transient disturbance of taste, oral desquamation, swelling of the parotid gland.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
See **SIDE EFFECTS** and **WARNINGS AND SPECIAL PRECAUTIONS**. Adverse effects have been reported following overdosage. Symptoms include nausea, vomiting, sore throat, and abdominal pain. Adverse central nervous system effects have been reported following overdose. Symptoms of the central nervous system includes dizziness, hallucinations, agitation, anxiety, and irritability. There is no specific antidote for benzydamine and should excessive quantities be ingested the treatment should be symptomatic and supportive.
IDENTIFICATION
A clear, pinkish red liquid with an odour of peppermint/aniseed.
PRESENTATION
Oral Rinse: Clear plastic bottles containing 200 mℓ and 2 ℓ
Spray: Clear glass or plastic PET bottles containing 30 mℓ
STORAGE INSTRUCTIONS
Store in the carton, at or below 30 °C, in an upright position. Protect from light.
KEEP OUT OF REACH OF CHILDREN.
REGISTRATION NUMBER
31/16.4/0143
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: 02 October 2002
Date of latest revision: 17 February 2017
FINAL PRODUCT MANUFACTURER
Pharma-Q (Pty) Ltd, 50 Commando Road Industria, Johannesburg, South Africa
COUNTRY OF ORIGIN: South Africa

BOTSWANA
Scheduling status (**Oral Rinse**): 4
Pharmacological classification: ATC: A01A D02 Other agents for local oral treatment
ATC: A01A B03 – Anti-infectives for local oral treatment
License number: BOT 9800286

BOTSWANA
Scheduling status (**Spray**): 3
Pharmacological classification: ATC: A01A D02 Other agents for local oral treatment
ATC: A01A B03 – Anti-infectives for local oral treatment
License number: BOT 1402676

NAMIBIA
Scheduling status: NS1
Registration number: 04/16.4/0956

ZIMBABWE
Distribution category: Pharmacist Initiated Medicine (PIM)
Registration number: 99/20.3.4/3526 (**Oral Rinse**)
2015/20.3.4/4974 (**Spray**)

ZAMBIA
Category of distribution: General sale
Marketing Authorization No: 478/004L

Andolex®-C
Oral Rinse

SKEDULERINGSTATUS
S1
EIENDOMSNAAM EN DOSEERVORM
ANDOLEX-C ORAL RINSE
SAMESTELLING

Elke 15 mℓ bevat bensidamienhidrochloried	22,5 mg
Chloorheksidien glukonaat	18 mg
Bevat alkohol	9 % *v/v*

Bevat Suiker: Sorbitol Oplossing 3,75 g/15 mℓ
Ander bestanddele sluit in polioksiel 40 gehidrogeneerde kasterolie, pepermentolie, anyssaad geur, karmosien en gesuiwerde water.
FARMAKOLOGIESE KLASSIFIKASIE
A 16.4 Nasofaringiale en buko-faringiale antiseptikum
FARMAKOLOGIESE WERKING
Farmakodinamiese eienskappe
Bensidamienhidrochloried toon 'n lokale analgetiese en anti-inflammatoriese uitwerking deur selmembrane te stabiliseer en prostaglandien sintese te inhibeer. Chloorheksidien het antiseptiese en onsmettende eienskappe.
Farmakokinetiese eienskappe
Bensidamien:
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.
Chloorheksidien:
Sistemiese absorpsie is minimaal. Chloorheksidien word swak uit die spysverteringskanaal en vel geabsorbeer.
INDIKASIES
Vir die verligting van geringe infeksies en pynlike inflammatoriese kondisies van die mond en keel. Chloorheksidien in **ANDOLEX-C ORAL RINSE** verminder die ontwikkeling van plaak.
KONTRA-INDIKASIES
Pasiënte met 'n bekende hipersensitiwiteit vir bensidamien, chloorheksidien of enige ander bestanddeel van hierdie produk (sien **SAMESTELLING**). **ANDOLEX-C ORAL RINSE** word nie aanbeveel vir kinders onder 6 jaar nie.
WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Moenie insluk nie. Indien branderigheid of steeksensasie voorkom, kan **ANDOLEX-C ORAL RINSE** met water verdun word. Verhoed kontak met oë. Indien dit wel in kontak kom met die oë, spoel deeglik uit met water. Ononderbroke behandeling moet nie langer as 7 dae duur nie, behalwe onder mediese toesig.
Pasiënte met seldsame oorerflike toestand van sorbitol intoleransie moet nie ANDOLEX-C ORAL RINSE gebruik nie.
Bevat sorbitol wat 'n uitwerking op glukemiese beheer van pasiënte met diabetes mellitus kan hê.
Uitwerking op die vermoë om te bestuur en die gebruik van masjienerie
ANDOLEX-C ORAL RINSE het geen of 'n weglaatbare invloed op die vermoë om te bestuur of om masjienerie te gebruik.
INTERAKSIES
Anioniese bestanddele in sommige tandepasta is onverenigbaar met chloorheksidien. Dit word aangeraai om ten minste 30 minute te laat verloop tussen tandeborsel en die gebruik van **ANDOLEX-C ORAL RINSE** om sodoende nie die plaak-weerende effek van chloorheksidien te verminder nie.
SWANGERSKAP EN LAKTASIE
Die veiligheid van ANDOLEX-C ORAL RINSE gedurende swangerskap en laktasie is nie vasgestel nie.
DOSIS EN GEBRUIKSAANWYSINGS
Volwassenes
Gorrel:
Gorrel met 15 mℓ (ongeveer een eetlepel vol). Gorrel vir ten minste 30 sekondes lank, elke 1½ tot 3 uur , soos nodig. Die oplossing moet uitgespoeg word na gebruik en nie ingesluk word nie.
Spoelmiddel vir letsels in die mond:
15 mℓ (ongeveer een eetlepel vol) wat in die mond rondgespoel moet word vir ten minste 30 sekondes lank, elke 1½ tot 3 uur gedurende die dag, soos nodig. Die oplossing moet uitgespoeg word na gebruik.
Sproei:
5 tot 10 sproeie direk op die pynlike of ontsteekte area en sluk dan sagkens in. Herhaal elke 1½ tot 3 uur soos benodig.
ANDOLEX-C ORAL RINSE word in die algemeen onverdun gebruik, maar indien branderigheid voorkom, kan dit met water verdun word.
Kinders (6 tot 12 jaar)
Indien die kind kan gorrel - gorrel met 5 tot 15 mℓ elke 3 ure.
Gebruik andersins as 'n spoelmiddel - spoel met 5 tot 15 mℓ elke 3 ure.
Vermy enige kontak met die oë.

Hoe om u ANDOLEX-C sproei te reining en versorg:
Spoel die mondstuk na elke gebruik af om sporadiese verstoppings van die sproeibuis te voorkom. Spoel die mondstuk met warm, lopende water vir ten minste 30 sekondes af en laat die water deur die mondstuk loop. Dit is baie belangrik omdat die klein opening waar die medisyne uitkom somtyds verstop kan raak. Skud enige oormaat water af en los die mondstuk om heeltemal droog te word. Let op dat verstoppings as gevolg van medikasie-aanpakking meer waarskynlik sal voorkom as die mondstuk nie toegelaat word om deeglik droog te word nie. Die sproei moet in 'n regop posisie gebêre word.

NEWE-EFFEKTE
Immuunstelsel versteurings
Minder dikwels: Hipersensitiwiteitsreaksies, insluitend urtikarie, uitslag, brongospasma of laringospasma en fotodermatitis.
Frekwensie onbekend: Ernstige allergiese reaksie (anafilaktiese skok). Tekens sluit moeilike asemhaling, borspyn, 'n toe bors en/of duiseligheid/flou gevoel erge jeuk of opgehewe knoppe op die vel, swelling van die gesig, lippe, tong en/of keel in, en kan potensieel lewensgevaarlik wees.
Gastrointestinale versteurings
Frekwensie onbekend: Gastrointestinale versteurings.
Algemene versteurings en versteurings van die plek van toediening
Minder dikwels: Gevoelloosheid van mondweefsel en branderige sensasie, droë mond of dors, omkeerbare verkleuring van die tong en tande, verbygaande versteuring van smaak, afskilfering van die mond, swelling van die parotisklier.
BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Sien **NEWE-EFFEKTE** en **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**.
Newe-effekte is aangemeld na oordosering. Simptome sluit naarheid, braking, seer keel en abdominale pyn in. Sentrale senuweestelsel newe-effekte is gerapporteer na oordosering. Sentrale senuweestelsel simptome sluit duiseligheid, hallusinasies, angstigheid, agitasie en irritasie in. Daar is geen spesifieke teenmiddel vir bensidamien nie, en as oormatige hoeveelhede ingesluk word, moet behandeling simptomaties en ondersteunend wees.
IDENTIFIKASIE
Helder, pienk tot rooi gekleurde vloeistof met 'n peperment/anys reuk.
AANBIEDING

Mondspoelmiddel:	Helder plastiek bottels wat 200 mℓ en 2 ℓ bevat
Sproei:	Helder glas of plastiek PET bottels wat 30 mℓ bevat

BERGINGSAANWYSINGS
Bewaar regop in die oorspronklike verpakking teen of benede 30 °C
Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.
REGISTRASIENOMMER
31/16.4/0143
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: 02 Oktober 2002
Datum van laaste hersiening: 17 Februarie 2017
VERVAARDIGER
Pharma-Q (Pty) Ltd, 50 Commando Road Industria, Johannesburg, Suid-Afrika
OORSPRONG: Suid-Afrika

KENYA
Reg. No: 14787
Legal Category: Pharmacy Only

Andolex®-C
Oral Rinse

SCHEDULING STATUS
S1
PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
ANDOLEX-C ORAL RINSE, benzydamine hydrochloride 22,5 mg/15 mℓ and chlorhexidine 18 mg/15 mℓ solution.
Read all of this leaflet carefully because it contains important information for you.
ANDOLEX-C ORAL RINSE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use **ANDOLEX-C ORAL RINSE** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **ANDOLEX-C ORAL RINSE** 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-C ORAL RINSE CONTAINS
The active substances are benzydamine hydrochloride 22,5 mg and chlorhexidine gluconate 18 mg. **ANDOLEX-C ORAL RINSE** contains alcohol 9 % *v/v*.
Contains sugar: Sorbitol solution 3,75 g/15 mℓ
Other ingredients include polyoxyl 40 hydrogenated castor oil, peppermint oil, aniseed, carmoisine and purified water.
WHAT ANDOLEX-C ORAL RINSE IS USED FOR
ANDOLEX-C ORAL RINSE is used for the relief of painful inflammatory conditions of the mouth and throat. **ANDOLEX-C ORAL RINSE** helps to reduce the development of plaque.
BEFORE YOU USE ANDOLEX-C ORAL RINSE
Do not take/use ANDOLEX-C ORAL RINSE:
- if you are under 6 years old
- if you are pregnant
- if you are hypersensitive (allergic) to benzydamine, chlorhexidine or any of the other ingredients of **ANDOLEX-C ORAL RINSE**.
- Patients with the rare hereditary condition of sorbitol intolerance should not use ANDOLEX-C ORAL RINSE.
- **ANDOLEX-C ORAL RINSE** contains sorbitol which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Take special care with ANDOLEX-C ORAL RINSE
- if stinging or burning occurs. **ANDOLEX-C ORAL RINSE** can be diluted with water
- to avoid contact with the eyes. Should **ANDOLEX-C ORAL RINSE** come into contact with the eyes, wash out thoroughly with water
- your treatment should not exceed 7 days except under medical supervision.

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 health care professional for advice before using **ANDOLEX-C ORAL RINSE**.
Driving and using machinery
ANDOLEX-C ORAL RINSE has no or negligible influence on the ability to drive and use machines.
Important information about some of the ingredients of ANDOLEX-C ORAL RINSE
ANDOLEX-C ORAL RINSE contains alcohol.
Using other medicines with ANDOLEX-C ORAL RINSE
Always tell your healthcare professional if you are taking other medicine. (This includes complementary or traditional medicines.) Some of the toothpastes are not compatible with chlorhexidine. At least 30 minutes should be allowed to elapse between teeth brushing and rinsing with **ANDOLEX-C ORAL RINSE** in order to ensure that the antiplaque effect is not reduced.
HOW TO USE ANDOLEX-C ORAL RINSE
Do not share medicines prescribed for you with any other person. You should check with your doctor or pharmacist if you are unsure how to use **ANDOLEX-C ORAL RINSE**.
Adults
Gargle:
Gargle with 15 mℓ (approximately one tablespoon) for at least 30 seconds at 1½ to 3 hourly intervals, as needed. The solution should be expelled from the mouth after use.
Rinse for oral lesions:
15 mℓ (approximately one tablespoon) which should be held in the mouth and swirled around for at least 30 seconds, with repeat use every 1½ to 3 hours throughout the day, as needed. 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.
Children (6 to 12 years)
Use 5 to 15 mℓ as a gargle if able to do so, or as an oral rinse, every 3 hours.
Avoid contact with the eyes.

How to clean and care for your ANDOLEX-C spray:
Rinse the actuator spindle and nozzle after every use to avoid sporadic blockages of the spray tube. Rinse the spray tube in warm, running water for at least 30 seconds and let the water run through the spray tube. This is very important as sometimes the small opening where the medicine comes out can become blocked. Shake off the excess water and leave the spray tube to dry completely. Blockage from medication build-up is more likely to occur if the spray tube is not allowed to dry thoroughly. The spray should be stored in an upright position.

If you take more ANDOLEX-C ORAL RINSE than you should
You may experience the following:
- nausea and vomiting
- abdominal pain
- oesophageal irritation.

Central nervous system effects have been reported following overdose. Symptoms include:
- dizziness
- hallucinations
- agitation
- anxiety
- irritability.

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-C ORAL RINSE
Do not use a double dose to make up for a forgotten individual dose. Use the next dose as previously directed.
POSSIBLE SIDE EFFECTS
ANDOLEX-C ORAL RINSE 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 using **ANDOLEX-C ORAL RINSE** 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/faint, severe itching of the skin or raised lumps of the skin, swelling of the face, lips, tongue and throat
- if you experience difficulty to breathe (bronchospasm)
- if you experience difficulty to speak (laryngospasm)
- if you get hives or a rash
- if you are sensitive to light.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ANDOLEX-C ORAL RINSE**. 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 (gastro-intestinal disturbances)
- oral tissue numbness
- stinging sensation
- dryness of the mouth or thirst
- disturbance of taste
- light-headedness
- reversible discolouration of the teeth and tongue
- swelling of the salivary (parotid) glands
- shedding or scaling of the inside of your mouth (oral desquamation).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
STORING AND DISPOSING OF ANDOLEX-C ORAL RINSE
- Store at or below 30 °C in the carton
- Store in an upright position
- Protect from light
- Do not use after the expiry date stated on the label
- Return all unused medicine to your pharmacist.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
Do not dispose of unused medicine in drains or sewerage system (e.g. toilets).
PRESENTATION OF ANDOLEX-C ORAL RINSE
Oral Rinse: Bottles containing 200 mℓ and 2 ℓ
Spray: Bottles containing 30 mℓ
IDENTIFICATION OF ANDOLEX-C ORAL RINSE
A clear, pinkish red liquid with an odour of peppermint/aniseed.
REGISTRATION NUMBER
31/16.4/0143
NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER
iNova Pharmaceuticals (Pty) Ltd
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COUNTRY OF ORIGIN: South Africa

081243
A3895

Andolex®-C
Oral Rinse

SKEDULERINGSTATUS
S1
EIENDOMSNAAM, STERKTE EN DOSEERVORM
ANDOLEX-C ORAL RINSE, bensidamienhidrochloried 22,5 mg/15 mℓ en chloorheksidien 18 mg/15 mℓ oplossing.
Lees hierdie hele pamflet noukeurig deur omdat dit belangrike inligting bevat.
ANDOLEX-C ORAL RINSE is sonder 'n voorskrif beskikbaar om minder ernstige siektes te behandel. Nogtans moet **ANDOLEX-C ORAL RINSE** 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-C ORAL RINSE** 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-C ORAL RINSE BEVAT
Die aktiewe bestanddele is bensidamienhidrochloried 22,5 mg en chloorheksidien 18 mg.
ANDOLEX-C ORAL RINSE bevat alkohol 9 % *v/v*.
Bevat Suiker: Sorbitol Oplossing 3,75 g/15 mℓ
Ander bestanddele sluit in polioksiel 40 gehidrogeneerde kasterolie, pepermentolie, anyssaad geur, karmosien en gesuiwerde water.
WAARVOOR ANDOLEX-C ORAL RINSE GEBRUIK WORD
ANDOLEX-C ORAL RINSE word gebruik vir die verligting van pynlike, inflammatoriese toestande van die mond en keel.
ANDOLEX-C ORAL RINSE help om die vorming van plaak te verminder
VOORDAT U ANDOLEX-C ORAL RINSE GEBRUIK
Moenie ANDOLEX-C ORAL RINSE gebruik:
- indien jy onder 6 jaar oud is nie
- indien jy swanger is nie
- indien jy hipersensitief (allergies) vir bensidamienhidrochloried, chloorheksidien of enige van die ander bestanddele van **ANDOLEX-C ORAL RINSE** is nie.
- Pasiënte met die seldsame oorerflike toestand van sorbitol intoleransie moet nie ANDOLEX-C ORAL RINSE neem nie.
- **ANDOLEX-C ORAL RINSE** bevat sorbitol wat 'n uitwerking op die beheer van u bloedsuiker kan hê indien u diabetes mellitus het.

Wees besonder versigtig met ANDOLEX-C ORAL RINSE
- as branderigheid voorkom. **ANDOLEX-C ORAL RINSE** kan met water verdun word
- om kontak met die oë te verhoed. Indien **ANDOLEX-C ORAL RINSE** in kontak kom met jou oë, moet dit deeglik met water uitgewas word
- jou behandeling moet nie langer as 7 dae duur nie, behalwe onder mediese toesig.

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-C ORAL RINSE** gebruik.
Motorbestuur en gebruik van masjinerie
ANDOLEX-C ORAL RINSE het geen of 'n weglaatbare effek op die vermoë om te bestuur en om masjiene te bedryf.
Belangrike inligting rakende sommige van die bestanddele in ANDOLEX-C ORAL RINSE
ANDOLEX-C ORAL RINSE bevat alkohol.
Gebruik van ander medisyne saam met ANDOLEX-C ORAL RINSE
Stel altyd jou gesondheidskundige in kennis as jy enige ander medisyne gebruik.
(Dit sluit komplementêre en tradisionele medisyne in.)
Sommige tandepastas is nie verenigbaar met chloorheksidien nie. Ten minste 30 minute moet tussen tandeborsel en die spoel met **ANDOLEX-C ORAL RINSE** verloop om te verseker dat die plaakwerende effek nie verminder word nie.
HOE OM ANDOLEX-C ORAL RINSE TE GEBRUIK
Moenie medisyne wat vir jou voorgeskryf is aan enige iemand anders gee nie.
Raadpleeg jou dokter of apteker as jy onseker is hoe om **ANDOLEX-C ORAL RINSE** te gebruik.
Volwassenes
Gorrel:
Gorrel met 15 mℓ (ongeveer een eetlepel vol) vir ten minste 30 sekondes lank in 1½ tot 3 uurlikse intervalle, soos benodig. Die oplossing moet uitgespoeg word na gebruik.
Spoel vir orale letsels:
15 mℓ (ongeveer een eetlepel vol) moet in die mond gehou word en rond geskommel word vir ten minste 30 sekondes in 1½ tot 3 uurlikse intervalle soos benodig deur die dag. Die oplossing moet uit die mond gespoeg word na gebruik.
Sproei:
Spuit 5 tot 10 sproeie direk op die pynlike of ontsteekte area. Sluk sagkuns in. Herhaal in 1½ tot 3 uurlikse intervalle soos benodig.
Kinders (6 tot 12 jaar)
Gebruik 5 tot 15 mℓ as 'n gorrel indien dit moontlik is of as 'n spoelmiddel elke 3 uurliks. Vermy kontak met die oë.

Hoe om jou ANDOLEX-C sproei te reinig en te versorg:
Spoel die mondstuk na elke gebruik af om sporadiese verstoppings van die sproeibuis te voorkom. Spoel die mondstuk met warm, lopende water vir ten minste 30 sekondes af en laat die water deur die mondstuk loop. Dit is baie belangrik omdat die klein opening, waardeur die medisyne uitkom, somtyds verstop kan raak. Skud enige oormaat water af en los die mondstuk om heeltemal droog te word. Verstoppings as gevolg van medikasie-aanpakking is meer waarskynlik indien die mondstuk nie toegelaat word om deeglik droog te word nie. Die sproei moet in 'n regop posisie gebêre word.

As jy meer ANDOLEX-C ORAL RINSE gebruik as wat jy moet
Jy kan die volgende simptome ervaar:
- naarheid en braking
- abdominale pyn
- slukderm irritasie.

Sentrale senuweestelsel effekte was al gerapporteer na oordosering. Die simptome sluit die volgende in:
- duiseligheid
- hallusinasies
- aggressie
- angstigheid
- irritasie.

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-C ORAL RINSE 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-C ORAL RINSE 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-C ORAL RINSE** gebruik, moet jy jou dokter, apteker of ander gesondheidskundige vir advies raadpleeg. Indien enige van die volgende voorkom, staak onmiddelik die gebruik van **ANDOLEX-C ORAL RINSE** en stel jou dokter dadelik in kennis of gaan na die 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 asem te haal (brongospasma)
- indien jy sukkel om te praat (laringospasma)
- indien jy galbulte of 'n uitslag kry
- indien jy sensitief is vir lig.

Bogenoemde is almal baie ernstige newe-effekte. Indien jy een van hulle ervaar, kon jy dalk 'n ernstige allergiese reaksie teenoor **ANDOLEX-C ORAL RINSE** gehad het. Jy kan ernstige mediese aandag of hospitalisasie benodig.
Stel jou dokter so gou moontlik in kennis indien jy een van die volgende opmerk:
- naarheid en braking (gastro-intestinale versteurings)
- gevoelloosheid van mondweefsel
- branderige sensasie
- droë mond of dors
- smaakversteurings
- lighoofdigheid
- omkeerbare verkleuring van die tande en tong
- swelling van die speekselkliere
- afskilfering aan die binnekant van jou mond.

Stel jou dokter of apteker in kennis indien jy enige newe-effekte opmerk wat nie in hierdie pamflet ingesluit is nie.
BERGING EN WEGDOENING VAN ANDOLEX-C ORAL RINSE
- Bewaar teen of benede 30 °C in die kartonhouer
- Bewaar in 'n regop posisie
- Beskerm teen lig
- Moenie die produk na die vervaldatum aangedui op die etiket gebruik nie
- Gee alle ongebruikte medisyne terug aan jou apteker.

BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.
AANBIEDING VAN ANDOLEX-C ORAL RINSE
Mondspoelmiddel: Bottels wat 200 mℓ en 2 ℓ bevat
Sproei: Bottels wat 30 mℓ bevat
IDENTIFIKASIE VAN ANDOLEX-C ORAL RINSE
'n Helder, pienk tot rooi gekleurde vloeistof met 'n peperment/anys reuk
REGISTRASIENOMMER
31/16.4/0143
NAAM EN ADRES VAN DIE HOUER VAN REGISTRASIE
iNova Pharmaceuticals (Pty) Ltd
Rileyweg 15E, Bedfordview, 2007
DATUM VAN PUBLIKASIE
Datum van registrasie: 02 Oktober 2002
Datum van laaste hersiening: 17 Februarie 2017
VERVAARDIGER
Pharma-Q (Pty) Ltd, 50 Commando Road Industria, Johannesburg, Suid-Afrika
OORSPRONG: Suid-Afrika

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Pro-Print