SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

ORANIX Solution

COMPOSITION

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

Other ingredients include sorbitol solution, polyoxyl 40 hydrogenated castor oil, peppermint oil, aniseed, carmoisine and purified water. SUGAR FREE.

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 **ORANIX** 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**).

ORANIX is not recommended in children under 6 years of age.

WARNINGS AND SPECIAL PRECAUTIONS

Do not swallow. If a burning or stinging sensation occurs, **ORANIX** 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.

Effects on ability to drive and use machines:

ORANIX 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 **ORANIX**.

PREGNANCY AND LACTATION

The safety of ORANIX 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.

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

Children (6 years and older)

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 ORANIX 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

Clear glass bottles containing 200 mℓ.

Clear Polyethylene Terephthalate (PET) bottles containing 200 mℓ, and 30 mℓ. Amber PET bottles containing 2 ℓ.

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

34/16.4/0391

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

11 October 2001

LT097.098.08.17

080912

SKEDULERINGSTATUS

S1

EIENDOMSNAAM EN DOSEERVORM

ORANIX Oplossing

SAMESTELLING

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

Ander bestanddele sluit in sorbitol oplossing, polioksiel 40 gehidrogeneerde kasterolie, pepermentolie, anyssaad geur, karmosien en gesuiwerde water. SUIKER VRY.

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 ontsmettings 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 **ORANIX** verminder die ontwikkeling van plaak.

KONTRA-INDIKASIES

Pasiënte met 'n bekende hipersensitiwiteit vir bensidamien, chloorheksidien of enige ander bestanddeel van hierdie produk (sien **SAMESTELLING**). **ORANIX** word nie aanbeveel vir kinders onder 6 jaar nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

Moenie insluk nie. Indien branderigheid of steeksensasie voorkom, kan **ORANIX** 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.

Uitwerking op die vermoë om te bestuur en die gebruik van masjienerie:

ORANIX 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 wag tussen tandeborsel en die gebruik van **ORANIX** om sodoende nie die plaak-weerende effek van chloorheksidien te verminder nie.

SWANGERSKAP EN LAKTASIE

Die veiligheid van ORANIX 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.

ORANIX word in die algemeen onverdun gebruik, maar indien branderigheid voorkom, kan dit met water verdun word.

Kinders (6 jaar en ouer)

Indien die kind kan gorrel - gorrel met 5 tot 15 m elke 3 ure.
Gebruik andersins as 'n spoelmiddel - spoel met 5 tot 15 m elke 3 ure.
Vermy enige kontak met die oë.

Hoe om u ORANIX sproei te reinig 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 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

Kleurlose glas bottels wat 200 mℓ bevat. Kleurlose poli-etileen tereptalaat (PET) bottels wat onderskeidelik 200 mℓ en 30 mℓ bevat. Amber kleurige PET bottels wat 2 ℓ bevat.

BERGINGSAANWYSINGS

Bewaar regop in die oorspronklike verpakking teen of benede 30°C. Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER

34/16.4/0391

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

iNova Pharmaceuticals (Pty) Ltd
Rileyweg 15E, Bedfordview, 2007

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET

11 Oktober 2001

Pro-Print