

SCHEDULING STATUS**S1****PROPRIETARY NAME AND DOSAGE FORM****ORANIX****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 **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.

Patients with the rare hereditary condition of sorbitol intolerance should not use **ORANIX**.

Contains sorbitol which may have an effect on blood sugar levels in patients with Diabetes Mellitus.

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 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 **ORANIX:**

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 overdose.

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**

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

Date of registration: 11 October 2001

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS**S1****PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

ORANIX, 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.

ORANIX is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use **ORANIX** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **ORANIX** 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 **ORANIX CONTAINS**

The active substances are benzydamine hydrochloride 22,5 mg and chlorhexidine gluconate 18 mg. **ORANIX** 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 **ORANIX IS USED FOR**

ORANIX is used for the relief of painful inflammatory conditions of the mouth and throat. **ORANIX** helps to reduce the development of plaque.

BEFORE YOU USE **ORANIX****Do not take/use **ORANIX**:**

- 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 **ORANIX**.
- Patients with the rare hereditary condition of sorbitol intolerance should not use **ORANIX**.
- **ORANIX** contains sorbitol which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Take special care with **ORANIX**

- if stinging or burning occurs. **ORANIX** can be diluted with water
- to avoid contact with the eyes. Should **ORANIX** 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 **ORANIX**.

Driving and using machinery

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

Important information about some of the ingredients of **ORANIX**

ORANIX contains alcohol.

Using other medicines with **ORANIX**

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 **ORANIX** in order to ensure that the antiplaque effect is not reduced.

HOW TO USE **ORANIX**

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 **ORANIX**.

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 **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. 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 **ORANIX 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 **ORANIX**

Do not use a double dose to make up for a forgotten individual dose. Use the next dose as previously directed.

POSSIBLE SIDE EFFECTS****ORANIX** 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 **ORANIX** 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 on 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 **ORANIX**. 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 **ORANIX**

- 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 **ORANIX**

Oral Rinse: Bottles containing 200 mL and 2 L

Identification: Bottles containing 30 mL

IDENTIFICATION OF **ORANIX**

A clear, pinkish red liquid with an odour of peppermint/aniseed.

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