**SCHEDULING STATUS**

S1

## 1. NAME OF THE MEDICINE

ORANIX, 22,5 milligram, 18 milligram, Solution.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 ml contains:

Benzydamine hydrochloride 22,5 mg and Chlorhexidine gluconate 18 mg

ORANIX contains 9 % *v/v* alcohol.

ORANIX contains sugar: Sorbitol 70 % 3,75 g/15 ml.

SUGAR FREE.

For the full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Solutions**.**

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

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For the relief of minor infections and painful inflammatory conditions of the mouth and throat. Chlorhexidine in ORANIX Solution helps to reduce the development of plaque.

### 4.2 Posology and method of administration

**Posology**

When used as a gargle, the usual dose is 15 ml (Approximately one tablespoon) which should be gargled for at least 30 seconds at 1½ to 3 hourly intervals, as needed.

When used as a rinse for oral lesions, the usual dose is again 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.

When used as a spray, the usual dose is 5 to 10 sprays directly onto the painful or inflamed area and swallow gently. Repeat every 1½ to 3 as necessary.

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

**Paediatric population**

Children (6 to 12 years)

5 to 15 ml as a gargle if able to do so, or as an oral rinse, every 3 hours.

**Method of administration**

Used as an oral gargle, rinse or spray.

**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.

**4.3 Contraindications**

Patients with known hypersensitivity to benzydamine, chlorhexidine or to any of the components of the vehicle or listed in section 6.

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

The safety in pregnancy and lactation has not been established. Refer to section 4.6.

**4.4 Special warnings and precautions for use**

Uninterrupted treatment should not exceed 7 days except under medical supervision.

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.

The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.

The content of sorbitol in medicines for oral use may affect the bioavailability of other medicines for oral use administered concomitantly.

Patients with hereditary fructose intolerance (HFI) should not take/be given this medicine.

**4.5 Interactions with other medicines and other forms of interactions**

Anionic agents are incompatible with Chlorhexidine.

Refer to section 4.3 and section 4.4 above.

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 solution.

**4.6 Fertility, pregnancy and lactation**

**Pregnancy**

The safety in pregnancy has not been established. Refer to section 4.3.

**Breastfeeding**

The safety in lactation has not been established. Refer to section 4.3.

### 4.7 Effects on ability to drive and use machines

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

### 4.8 Undesirable effects

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|---|---|---|
| **Immune system disorders** | Less frequent | Hypersensitivity, with urticaria, pruritus rash, bronchospasm or laryngospasm and photodermatitis |
| | Unknown frequency | 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** | Less frequent | Oral numbness.<br>Dryness or thirst, gastro-intestinal disturbances, tingling, warm feeling in the mouth and altered sense of taste. Burning or stinging sensation in mouth. Reversible discolouration of the tongue and teeth, oral desquamation, occasional swelling of the parotid gland have been reported. |

*Reporting of suspected adverse reactions*

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

### 4.9 Overdose

See section 4.8 and section 4.4. Adverse central nervous system effects have been reported following overdosage with high doses of ORANIX. Symptoms include nausea, vomiting, sore throat, and abdominal pain. There is no specific antidote for benzydamine and should excessive quantities be ingested the treatment should be symptomatic and supportive.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

A.16.4 Nasopharyngeal and bucco-pharyngeal antiseptics.

Benzydamine hydrochloride has local analgesic and anti-inflammatory properties through stabilising the cellular membrane and inhibiting prostaglandin synthesis. Chlorhexidine has antiseptic and disinfectant properties.

### 5.2 Pharmacokinetic properties

**Benzydamine:**

When administered as local application, it has a low systemic absorption and should reduce the potential of systemic drug 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.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Aniseed liquid flavour

Carmoisine

Ethanol 96 %

Peppermint oil

Polyoxyl 40 hydrogenated castor oil

Purified water

Sorbitol solution 70 %

**6.2 Incompatibilities**

None

**6.3 Shelf life**

36 months.

**6.4 Special precautions for storage**

Store in the carton, at or below 30 °C.

Protect from light.

Keep well closed.

**6.5 Nature and contents of container**

Oral Rinse:  Clear glass bottles containing 200 ml and 2 litres.

Clear Polyethylene Terephthalate (PET) bottle containing 200 ml.

Spray:  Clear PET bottles with spray actuator containing 30 ml.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Limited

15e Riley Road

Bedfordview

Gauteng

South Africa

## 8. REGISTRATION NUMBER

34/16.4/0391

## 9. DATE OF FIRST AUTISATATION/RENEWAL OF AUTHORISATION

11 October 2001.

## 10. DATE OF REVISION OF THE TEXT

18 October 2021.