PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

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

ORANIX contains 9 % *v/v* alcohol

ORANIX contains sugar (sorbitol 70 %, 3,75 g/15 ml)

ORANIX is sugar free

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 healthcare provider or 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 is in this leaflet

1. What ORANIX is and what it is used for
2. What you need to know before you use ORANIX
3. How to use ORANIX
4. Possible side effects
5. How to store ORANIX
6. Contents of the pack and other information

1. What ORANIX is and what it is used for

ORANIX contains are benzydamine hydrochloride 22,5 mg and chlorhexidine gluconate 18 mg.

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

2. What you need to know before you use ORANIX

Do not use ORANIX:

- If you are hypersensitive (allergic) to benzydamine or chlorhexidine gluconate or any of the other ingredients of ORANIX (listed in section 6).
- If you are under 6 years old.
- If you are pregnant or breastfeeding your baby.

Warnings and Precautions

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.

Other medicines and ORANIX

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines may be affected by ORANIX. These include:

- 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.

ORANIX contains 3,75 g sorbitol solution in each 15 ml, which is equivalent to 2,653 g/volume.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) receive this medicine.
Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

ORANIX with food and drink

ORANIX should be gargled.

Pregnancy, breastfeeding and fertility

Safety in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using ORANIX.

Driving and using machines

It is not always possible to predict to what extent ORANIX may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which ORANIX

affects you.

3. How to use ORANIX

Do not share medicines prescribed for you with any other person.

Always use ORANIX exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is:

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.

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.

If you use more ORANIX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use ORANIX



Do not take a double dose to make up for a forgotten individual dose.

4. Possible side effects

ORANIX can have side effects.

Not all side effects reported for ORANIX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ORANIX, please consult your healthcare provider for advice.

If any of the following happens, stop taking ORANIX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ORANIX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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 spasm in the muscle spasm of the vocal cords
- dizziness
- if you get hives or a rash

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- abdominal pain
- oesophageal irritation
- if you are sensitive to light
- oral tissue numbness
- stinging sensation
- dryness of the mouth or thirst
- disturbance of taste
- gastrointestinal disturbances
- 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.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ORANIX.

5. How to store ORANIX

- Store all medicines out of reach of children.
- Store at or below 30 °C and protect from light. Keep well closed.
- Do not use after the expiry date stated on the blister and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ORANIX contains

The active substances in ORANIX solution are benzydamine hydrochloride 22,5 mg and chlorhexidine gluconate 18 mg.

The other ingredients include aniseed liquid flavour, carmoisine, ethanol 96 %, peppermint oil, polyoxyl 40 hydrogenated castor oil, purified water, sorbitol solution 70 %.

What ORANIX looks like and contents of the pack

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

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.

Holder of Certificate of Registration

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