

## Patient Information Leaflet

### SCHEDULING STATUS

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### **SEPTADINE® ORAL ANTISEPTIC (SOLUTION)**

Povidone Iodine 1,00 g (1 % *m/v*) equivalent to 0,1 % *m/v* available iodine

Contains 8,5 % *v/v* alcohol

Sugar Free, artificially sweetened

**Read all of this leaflet carefully because it contains important information for you**

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

- Keep this leaflet. You may need to read it again.
- Do not share **SEPTADINE® ORAL ANTISEPTIC** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

### **What is in this leaflet**

1. What **SEPTADINE® ORAL ANTISEPTIC** is and what it is used for
2. What you need to know before you take **SEPTADINE® ORAL ANTISEPTIC**
3. How to take **SEPTADINE® ORAL ANTISEPTIC**
4. Possible side effects
5. How to store **SEPTADINE® ORAL ANTISEPTIC**
6. Contents of the pack and other information

## **1. WHAT SEPTADINE® ORAL ANTISEPTIC IS USED FOR**

**SEPTADINE® ORAL ANTISEPTIC** is recommended for relief of painful infections and inflammatory conditions of the mouth and pharynx, and as a routine mouthwash. It can also be used for prevention of infections during and after oral surgery.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU USE SEPTADINE® ORAL ANTISEPTIC**

### **Do not use SEPTADINE® ORAL ANTISEPTIC:**

- if you are hypersensitive to povidone-Iodine
- if you suffer from any thyroid disorders
- if you have a goiter
- if you are pregnant or breastfeeding

### **Warnings and precautions**

#### **Take special care with SEPTADINE® ORAL ANTISEPTIC**

- if irritation, swelling or redness occurs
- if you have a severe or persistent sore throat, or sore throat accompanied by high fever, headache, nausea and vomiting.
- if you suffer from any thyroid disorders, it may interfere with thyroid function tests.

### **Children and adolescents**

For children under 3 years: Dilute one part **SEPTADINE® ORAL ANTISEPTIC** with three parts water and paint the mouth with the aid of a cotton-bud.

### **Other medicines and SEPTADINE® ORAL ANTISEPTIC**

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

The absorption of iodine from **SEPTADINE® ORAL ANTISEPTIC** may interfere with thyroid function tests and can make a planned treatment of the thyroid with iodine (radioiodine therapy) impossible.

Regular or prolonged use of **SEPTADINE® ORAL ANTISEPTIC** should be avoided if you are receiving lithium therapy, as it can interfere with lithium.

#### **Using SEPTADINE® ORAL ANTISEPTIC with food and drink:**

The use of **SEPTADINE® ORAL ANTISEPTIC** with food and drink has not been established.

#### **Pregnancy, breast-feeding and fertility**

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 being taking this medicine.

**SEPTADINE® ORAL ANTISEPTIC** should not be used in pregnancy or by lactating women

#### **Driving and using machines**

It is not always possible to predict to what extent **SEPTADINE® ORAL ANTISEPTIC** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **SEPTADINE® ORAL ANTISEPTIC** affects them.

### **3. HOW TO USE SEPTADINE® ORAL ANTISEPTIC**

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

Always take **SEPTADINE® ORAL ANTISEPTIC** exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Do not swallow **SEPTADINE® ORAL ANTISEPTIC**.

**As a mouthwash:** Dilute one part of **SEPTADINE® ORAL ANTISEPTIC** with two parts of water, rinse mouth thoroughly and spit out, or use as directed by physician or dentist.

**For infections of mouth and throat:** Use full strength and rinse or gargle for 30 seconds then spit out, repeat hourly, or as directed by physician or dentist.

**For children under 3 years:** Dilute one part **SEPTADINE® ORAL ANTISEPTIC** with three parts water and paint the mouth with the aid of a cotton-bud.

#### **If you use more SEPTADINE® ORAL ANTISEPTIC than you should**

If you use more than you should, treatment will be dependent on the symptoms you experience.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

#### **If you forget to use SEPTADINE® ORAL ANTISEPTIC**

The effects of missing a dose of **SEPTADINE® ORAL ANTISEPTIC** has not been established.

#### **If you stop using SEPTADINE® ORAL ANTISEPTIC**

If you are unsure when to stop using **SEPTADINE® ORAL ANTISEPTIC**, consult your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

Not all side effects reported for **SEPTADINE® ORAL ANTISEPTIC** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **SEPTADINE® ORAL ANTISEPTIC**, please consult your health care provider for advice.

If any of the following happen, you should stop taking **SEPTADINE® ORAL ANTISEPTIC** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema)
- Skin rashes or itching (pruritus)
- Itchy rash (urticaria)

These are very serious side effects. If you have them you may have had a serious allergic reaction or other type of reaction to **SEPTADINE® ORAL ANTISEPTIC**. 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:

- If you suffer from a thyroid disorder and notice any changes.

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

Tell your doctor if you notice any of the following:

##### Frequency unknown side effects:

- Headache
- Nausea
- Vomiting

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 **SEPTADINE® ORAL ANTISEPTIC**.

## **5. HOW TO STORE SEPTADINE® ORAL ANTISEPTIC**

Store all medicines out of reach of children

- Store at or below 25 °C. Protect from light.
- Do not store in bathrooms in order to protect from light.
- Do not take use medicine after the expiry date stated on the label.
- 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 SEPTADINE® ORAL ANTISEPTIC CONTAINS**

The active substance is Povidone-Iodine.

Each 100 ml contains: Povidone-Iodine 1,00 g (1 % *m/v*) equivalent to 0,1 % *m/v* available iodine.

Contains 8,5 % *v/v* alcohol

Sugar free, artificially sweetened.

The other ingredients are:

Anhydrous disodium hydrogen phosphate, citric acid anhydrous, ethanol, polyethylene glycol 400, purified water, saccharin sodium.

**What SEPTADINE® ORAL ANTISEPTIC looks like and the contents of the pack**

**SEPTADINE® ORAL ANTISEPTIC** is a clear dark-brown aqueous solution with a characteristic iodine smell, and a pleasant flavour.

Bottles of 200 ml and 2,5 litres.

**Holder of Certificate of Registration**

Ranbaxy Pharmaceuticals (Pty) Ltd

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1724

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<b>NSO</b> 04/16.4/1620 (Namibia) 200ml
GS 168/016(Zambia) 200 ml