

Patient Information Leaflet

SCHEDULING STATUS

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SEPTADINE® ANTISEPTIC OINTMENT (OINTMENT)

Each 10 g contains 1 g Povidone-Iodine in a water miscible base.

Available iodine: 250 mg/25 g of ointment.

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

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

- Keep this leaflet. You may need to read it again.
- Do not share **SEPTADINE® ANTISEPTIC OINTMENT** 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® ANTISEPTIC OINTMENT** is and what it is used for
2. What you need to know before you use **SEPTADINE® ANTISEPTIC OINTMENT**
3. How to use **SEPTADINE® ANTISEPTIC OINTMENT**
4. Possible side effects
5. How to store **SEPTADINE® ANTISEPTIC OINTMENT**
6. Contents of the pack and other information

1. WHAT SEPTADINE® ANTISEPTIC OINTMENT IS USED FOR

SEPTADINE® ANTISEPTIC OINTMENT is used as an antiseptic in the treatment of skin infections, pressure sores, wounds, cuts, abrasions, burns and for post-operative wounds.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SEPTADINE® ANTISEPTIC OINTMENT

Do not use SEPTADINE® ANTISEPTIC OINTMENT:

- if you are hypersensitive to povidone-Iodine
- if you have a goiter
- if you are pregnant or breastfeeding
- if you have a large area of broken skin (eg. Severe and extensive burn)

Warnings and precautions

Take special care with SEPTADINE® ANTISEPTIC OINTMENT

- if irritation, swelling or redness occurs
- if you are using it on a new born baby
- if you suffer from any thyroid disorders, it may interfere with thyroid function tests.

Children and adolescents

If used in neonates, it may result in an underactive thyroid gland function.

Other medicines and SEPTADINE® ANTISEPTIC OINTMENT

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® ANTISEPTIC OINTMENT** may interfere with thyroid function tests.

SEPTADINE® ANTISEPTIC OINTMENT should be avoided if you are receiving lithium therapy, as it can reduce your thyroid function.

Using SEPTADINE® ANTISEPTIC OINTMENT with food and drink:

The use of **SEPTADINE® ANTISEPTIC OINTMENT** 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® ANTISEPTIC OINTMENT 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® ANTISEPTIC OINTMENT** 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® ANTISEPTIC OINTMENT** affects them.

3. HOW TO USE SEPTADINE® ANTISEPTIC OINTMENT

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

Always take **SEPTADINE® ANTISEPTIC OINTMENT** 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® ANTISEPTIC OINTMENT**.

The affected area should be cleaned and dried. Apply to affected areas twice daily or as directed. An occlusive dressing may be used if necessary.

If you use more SEPTADINE® ANTISEPTIC OINTMENT 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® ANTISEPTIC OINTMENT

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

If you stop using SEPTADINE® ANTISEPTIC OINTMENT

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

4. POSSIBLE SIDE EFFECTS

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

If any of the following happen, you should stop taking **SEPTADINE® ANTISEPTIC OINTMENT** 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® ANTISEPTIC OINTMENT**. 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:

- Local Irritation
- Swelling
- Redness

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® ANTISEPTIC OINTMENT.

5. HOW TO STORE SEPTADINE® ANTISEPTIC OINTMENT

Store all medicines out of reach of children

- Store at or below 25 °C. Keep tightly closed.
- 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® ANTISEPTIC OINTMENT CONTAINS

The active substance is Povidone-Iodine.

Each 10 g contains 1 g Povidone-Iodine in a water miscible base.

Available iodine: 250 mg/25 g of ointment.

Sugar free

The other ingredients are:

Polyethylene glycol 400, polyethylene glycol 4000, purified water, sodium hydroxide.

What SEPTADINE® ANTISEPTIC OINTMENT looks like and the contents of the pack

SEPTADINE® ANTISEPTIC OINTMENT is a smooth, amber coloured ointment with a characteristic iodine odour.

25 g tubes, 50 g tubes and 500 g jars.

Holder of Certificate of Registration

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1724

This leaflet was last revised in

24 August 2022

Registration Number

28/14.1/ 0651 (S.A)

(S3)BOT 0500772 (Botswana)

04/14.1/1005 (Namibia)

GS 168/017 (Zambia)