

**PATIENT INFORMATION LEAFLET FOR
DERMADINE ANTISEPTIC OINTMENT**

Scheduling Status

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DERMADINE ANTISEPTIC OINTMENT (OINTMENT)

Each 25 g contains 2,5 g Povidone-iodine which is equivalent to 1% of available iodine, in a water miscible base.

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

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

- Keep this leaflet. You may need to read it again.
- Do not share DERMADINE ANITSEPTIC 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 DERMADINE ANTISEPTIC OINTMENT is and what it is used for
2. What you need to know before you take DERMADINE ANTISEPTIC OINTMENT
3. How to take DERMADINE ANTISEPTIC OINTMENT
4. Possible side effects
5. How to store DERMADINE ANTISEPTIC OINTMENT

6. Contents of the pack and other information.

1. What DERMADINE ANTISEPTIC OINTMENT is and what it is used for

DERMADINE ANTISEPTIC OINTMENT is used as a general antiseptic in the treatment of skin infections, wounds, cuts abrasions, burns if not extensive, bedsores and for post-operative wounds.

2. What you need to know before you take DERMADINE ANTISEPTIC OINTMENT

Do not use DERMADINE ANTISEPTIC OINTMENT if you:

- are hypersensitive (allergic) to povidone-iodine or any of the other ingredients of DERMADINE ANTISEPTIC OINTMENT (listed in **Section 6**).
- if you have a goitre
- if you are pregnant or breastfeeding
- if you have a large area of broken skin (e.g., Severe, and extensive burn)

Warnings and Precautions

Take special care with DERMADINE ANTISEPTIC OINTMENT:

- not to be used by persons allergic to iodine
- if irritation, swelling, or redness occurs
- if you are using it on a newborn 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 DERMADINE ANTISEPTIC OINTMENT

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

The absorption of iodine from DERMADINE ANTISEPTIC OINTMENT through either intact or broken skin may interfere with thyroid function tests.

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

DERMADINE ANTISEPTIC OINTMENT with food, drink and alcohol

The use of DERMADINE ANTISEPTIC OINTMENT with food and drink has not been established.

Pregnancy, breastfeeding and fertility

Do not use DERMADINE ANTISEPTIC OINTMENT if you are pregnant or breastfeeding your baby.

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

Driving and using machinery

It is not always possible to predict to what extent DERMADINE 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 DERMADINE ANTISEPTIC OINTMENT affects them.

3. How to use DERMADINE ANTISEPTIC OINTMENT

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

Always use DERMADINE ANTISEPTIC OINTMENT exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

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 DERMADINE ANTISEPTIC OINTMENT than you should

In the event of overdosage, consult your pharmacist or doctor. If neither is available, contact the nearest hospital or poison control center. Effects of metabolic acidosis (a condition in which too much acid accumulates in the body), a high concentration of sodium in the blood, and kidney failure may follow the application of povidone-iodine to severe burns or large areas otherwise denuded of skin.

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

If you forget to use DERMADINE ANTISEPTIC OINTMENT

The effects of missing a dose of DERMADINE ANTISEPTIC OINTMENT has not been established.

If you stop using DERMADINE ANTISEPTIC OINTMENT

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

4. Possible Side Effects

DERMADINE ANTISEPTIC OINTMENT can have side effects.

Not all side effects reported for DERMADINE ANTISEPTIC OINTMENT are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking

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DERMADINE ANTISEPTIC OINTMENT, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using ERMADINE ANTISEPTIC OINTMENT and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

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

Tell your doctor if you notice any of the following:

Side effects with unknown frequency:

- Local irritation
- Swelling
- Redness
- Hypothyroidism (underactive thyroid) may occur after topical application to neonates.
- Absorption of povidone-iodine may interfere with thyroid function tests.

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, 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> or by e-mail: drugsafety@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of DERMADINE ANTISEPTIC OINTMENT.

5. How to store DERMADINE ANTISEPTIC OINTMENT

- Store at or below 25 °C.
- Keep tightly closed
- For external use only.

Store all medicines out of reach of children.

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 DERMADINE ANTISEPTIC OINTMENT contains

The active substance is Povidone-iodine.

Each 25 g contains 2,5 g Povidone-iodine which is equivalent to 1% of available iodine, in a water miscible base.

The other ingredients are:

Polyethylene Glycol 400, polyethylene Glycol 4000, sodium hydroxide solution and purified water.

What DERMADINE ANTISEPTIC OINTMENT looks like and contents of the pack

DERMADINE ANTISEPTIC OINTMENT: A smooth, amber coloured ointment with a characteristic iodine odour.

DERMADINE ANTISEPTIC OINTMENT: is presented in 25g and 50g tubes and 500g jars.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Customer Care: 080 222 6662

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H.1049 (Act 101 /1965)

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.
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