PATIENT INFORMATION LEAFLET FOR

DERMADINE ORAL ANTISEPTIC

SCHEDULING STATUS: S0

DERMADINE ORAL ANTISEPTIC (solution)

Each 100 ml of DERMADINE ORAL ANTISEPTIC contains:

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

Contains Alcohol 8,85 % *v/v*

Contains sweetener: Saccharin sodium 0,07 g

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

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

- Keep this leaflet. You may need to read it again.
- Do not share DERMADINE 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 DERMADINE ORAL ANTISEPTIC is and what it is used for
2. What you need to know before you use DERMADINE ORAL ANTISEPTIC
3. How to use DERMADINE ORAL ANTISEPTIC

4. Possible side effects
5. How to store DERMADINE ORAL ANTISEPTIC
6. Contents of the pack and other information.

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

DERMADINE ORAL ANTISEPTIC is recommended for relief of painful infections and inflammatory conditions of the mouth and throat and as a routine mouthwash.

Infections

Mouth ulcers, inflammation of the gums, a sore or inflammation inside the mouth and a sore throat due to superficial infections. It can also be used for prevention of infections during and after oral surgery.

2. What you need to know before you use DERMADINE ORAL ANTISEPTIC

Do not use DERMADINE ORAL ANTISEPTIC if you:

- are hypersensitive (allergic) to povidone-iodine or any of the other ingredients of DERMADINE ORAL ANTISEPTIC (listed in **Section 6**),
- if you have a goiter,
- if you are pregnant or breastfeeding,
- if you suffer from any thyroid disorders.

Warnings and precautions

Take special care with DERMADINE 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.

Other medicines and DERMADINE 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 DERMADINE 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 DERMADINE ORAL ANTISEPTIC should be avoided if you are receiving lithium therapy, as it can interfere with lithium.

DERMADINE ORAL ANTISEPTIC with food, drink and alcohol

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

Pregnancy, breastfeeding 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 health care provider for advice before taking DERMADINE ORAL ANTISEPTIC.

DERMADINE ORAL ANTISEPTIC should not be used in pregnancy or breastfeeding.

Driving and using machines

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

3. How to use DERMADINE ORAL ANTISEPTIC

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

Always use DERMADINE ORAL ANTISEPTIC exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are not sure.

Your doctor will tell you how long your treatment with DERMADINE ORAL ANTISEPTIC will last.

If you have the impression that the effect of DERMADINE ORAL ANTISEPTIC is too strong or too weak, tell your doctor or pharmacist.

Do not swallow DERMADINE ORAL ANTISEPTIC.

As a mouthwash:

Dilute one part of DERMADINE ORAL ANTISEPTIC with two parts of water, rinse mouth thoroughly and spit out, or use as directed by doctor or dentist.

For infections of the mouth and throat:

Use full strength and rinse or gargle for thirty seconds then spit out, repeat hourly, or as directed by doctor or dentist.

For children under 3 years:

Dilute one part DERMADINE ORAL ANTISEPTIC with three parts water and paint the mouth with the aid of a cotton bud.

If you use more DERMADINE ORAL ANTISEPTIC than you should

If you accidentally swallow more than the recommended amount, it is important to get medical help immediately. Swallowing large amounts can cause serious health problems, including:

- A strong metallic taste in the mouth;
- feeling sick or vomiting;
- stomach pain and diarrhoea;
- difficulty passing urine (which may start 1 to 3 days later);
- breathing problems or chest discomfort;
- swelling in the throat, which can make it hard to breathe;
- in rare cases, serious complications such as kidney problems or changes in blood salts may occur.

If too much is swallowed, there is also a risk of damage to the food pipe (oesophagus), especially if not treated quickly.

Do not try to treat the overdose on your own. Get medical help immediately. Take the bottle or leaflet with you to show the doctor. Treatment will depend on the symptoms and may include supportive care to help the body recover.

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 DERMADINE ORAL ANTISEPTIC

If you forget to use DERMADINE ORAL ANTISEPTIC, use it as soon as you remember, unless it is almost time for your next dose.

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

Just continue with your regular dosing schedule after the missed dose.

If you often forget doses, talk to your doctor or pharmacist for advice or use reminders to help you.

If you stop using DERMADINE ORAL ANTISEPTIC

You can stop using DERMADINE ORAL ANTISEPTIC when your symptoms improve.

However, you must see a doctor if your symptoms worsen or do not improve.

Do not use the DERMADINE ORAL ANTISEPTIC for longer than recommended unless advised by a health care provider.

4. Possible side effects

DERMADINE ORAL ANTISPETIC can have side effects.

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

If any of the following happens, stop using DERMADINE ORAL ANTISEPTIC 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,

- severe or persistent sore throat accompanied by high fever, headache, nausea and vomiting.

These are all very serious side effects. If you have them, you may have had a serious reaction to DERMADINE 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:

Side effects with unknown frequency:

- irritation, swelling, redness
- 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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of DERMADINE ORAL ANTISEPTIC.

5. How to store DERMADINE ORAL ANTISEPTIC

Store at or below 25 °C.

Store all medicines out of reach of children.

Store in the original container.

Keep the container in the outer carton.

Do not use after the expiry date stated on the container.

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 ORAL ANTISEPTIC contains

The active substance is povidone-iodine. Each 100 ml of DERMADINE ORAL ANTISEPTIC contains povidone-Iodine 1,00 g (1 % *m/v*) equivalent to 0,1 % *m/v* available iodine.

The other ingredients are ethanol 96 %, citric acid-phosphate buffer, purified water, polyethylene glycol 400, saccharin sodium.

What DERMADINE ORAL ANTISEPTIC looks like and contents of the pack

DERMADINE ORAL ANTISEPTIC is a dark brown clear liquid.

DERMADINE ORAL ANTISEPTIC is presented in a bottle of 200 ml and 2,5 litre.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

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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.