**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS** **S0**

**BETADINE® ANTISEPTIC OINTMENT 10 % *w/w* (ointment)**

Povidone-iodine

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

- BETADINE® ANTISEPTIC OINTMENT is available without a doctor's prescription for you to treat a mild illness. Nevertheless, you still need to use BETADINE® ANTISEPTIC OINTMENT carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share BETADINE® ANTISEPTIC OINTMENT 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 BETADINE® ANTISEPTIC OINTMENT is and what it is used for
2. What you need to know before you use BETADINE® ANTISEPTIC OINTMENT
3. How to use BETADINE® ANTISEPTIC OINTMENT
4. Possible side effects
5. How to store BETADINE® ANTISEPTIC OINTMENT
6. Contents of the pack and other information


## 1. What BETADINE® ANTISEPTIC OINTMENT is and what it is used for

BETADINE® ANTISEPTIC OINTMENT contains povidone-iodine, which kills a wide range of germs, including bacteria, fungi, viruses and simple organisms.

BETADINE® ANTISEPTIC OINTMENT is used for the treatment or prevention of infections in minor wounds, cuts, abrasions, burns and ulcers.

## 2. What you need to know before you use BETADINE® ANTISEPTIC OINTMENT

**Do not use BETADINE® ANTISEPTIC OINTMENT:**

- If you are hypersensitive (allergic) to povidone-iodine or any of the other ingredients of BETADINE® ANTISEPTIC OINTMENT (listed in section 6).
- If you have any conditions affecting your thyroid.
- During radioiodine therapy for thyroid diseases.
- If you are using any products that contain mercury.
- If you are taking a medicine called lithium (used to treat depression).
- In children under 2 years of age.

**Warnings and precautions**

**Take special care with BETADINE® ANTISEPTIC OINTMENT:**

- If you have an allergic or irritant reaction such as redness, small blisters, itching or a rash. If this happens, you should stop using BETADINE® ANTISEPTIC OINTMENT and you should talk to your doctor or pharmacist.
- Do not heat BETADINE® ANTISEPTIC OINTMENT.
- You may experience a temporary change in colour of the skin in the area BETADINE® ANTISEPTIC OINTMENT was applied.
- For external use only.

**Children and adolescents**

Do not use in children under 2 years of age. BETADINE® ANTISEPTIC OINTMENT must only be applied by an adult.

Keep out of the reach of children.

**Other medicines and BETADINE® ANTISEPTIC OINTMENT**

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

In particular, you should tell your doctor or pharmacist if you are using the following:

- Lithium (medicine used for depression).
- Wound-treatment medicines containing enzymes, silver, hydrogen peroxide and taurolidine.
- Antiseptics containing octenidine.

Tell your doctor if you are due to have a thyroid test, faeces (stool) or urine test, as BETADINE® ANTISEPTIC OINTMENT may affect the results.

**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 using this medicine.

During pregnancy and lactation, BETADINE® ANTISEPTIC OINTMENT should only be used if strictly indicated and its use should be kept to the absolute minimum.

Because of the ability of iodine to pass through the placenta and be secreted in breast milk, and because of the increased sensitivity of the foetus and newborn to iodine, no large amounts of BETADINE® ANTISEPTIC OINTMENT should be used during pregnancy and lactation.

Do not apply BETADINE® ANTISEPTIC OINTMENT to your breast, if you are breastfeeding.

No information is available about the effects of using BETADINE® ANTISEPTIC OINTMENT on fertility.

**Driving and using machines**

BETADINE® ANTISEPTIC OINTMENT has no known effect on the ability to drive and use machines.

## 3. How to use BETADINE® ANTISEPTIC OINTMENT

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

Always use BETADINE® ANTISEPTIC OINTMENT exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

BETADINE® ANTISEPTIC OINTMENT is only to be applied to the skin.

The skin should be cleaned and dried before application.

If required, the affected area can be covered with a dressing or bandage.

If there is no improvement after 7 days of regular use, consult your doctor.

Apply the following amount of BETADINE ANTISEPTIC OINTMENT to the affected area for 7 to a maximum of 14 consecutive days.

- Children from 2-6 years: up to 2 pea sized amounts a day
- Children up to 7-8 years: up to 3 pea sized amounts a day
- Children from 9-14 years: up to 4 pea sized amounts a day
- Children from 15-18 years: up to 5 pea sized amounts a day
- Adults: 5-6 pea sized amounts a day

**If you use more BETADINE® ANTISEPTIC OINTMENT than you should**

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

Systemic absorption of iodine from BETADINE® ANTISEPTIC OINTMENT after repeated application to large areas of wounds or burns or deliberate or accidental ingestion of large quantities of BETADINE® ANTISEPTIC OINTMENT may lead to a number of overdose effects: metallic taste in mouth, increased saliva production, burning or pain in the throat or mouth, irritation and swelling of the eyes, pulmonary oedema (fluid in the lungs, making it difficult to breathe), skin reactions, upset stomach and diarrhoea, metabolic acidosis (high levels of acid in the body), high levels of sodium in the blood (seen with a test) and kidney problems.

If you experience any of the effects listed above, following the use of BETADINE® ANTISEPTIC OINTMENT, of following deliberate or accidental ingestion, you should contact your doctor, pharmacist or local hospital immediately. Take this leaflet and any other packaging with you so they know what you have been using.

**If you forget to use BETADINE® ANTISEPTIC OINTMENT**

Do not apply a double dose to make up for a forgotten dose, simply apply the next dose as planned. Then follow the original instructions for use.

## 4. Possible side effects

BETADINE® ANTISEPTIC OINTMENT can have side effects.

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

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

- Allergic type reactions that occur quickly and include an itchy raised skin rash (hives), a

body rash, sudden breathing problems, feeling faint, swelling of the mouth, face, lips, tongue and throat.

- Symptoms of an over-active thyroid - symptoms may include feeling nervous, moody, difficultly sleeping, hand tremors, fast or irregular heartbeat, trouble breathing, feeling very hot or sweaty, and weight loss.

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Skin redness and / or skin swelling, itching, small blisters.

The frequency of the following side effects is unknown:

- Hypothyroidism (insufficient function of thyroid gland, which can cause fatigue, weight gain, slow heart rate) - can occur due to prolonged or extensive use of BETADINE® ANTISEPTIC OINTMENT.
- The amount of electrolytes in your body is too high or too low (seen in a test) – can occur when large amounts of BETADINE® ANTISEPTIC OINTMENT are used.
- Increased amounts of acid in your blood (the main symptoms are shortness of breath, confusion and lethargy) – can occur when large amounts of BETADINE® ANTISEPTIC OINTMENT are used.
- Kidney failure (symptoms include difficulty in urinating, thirst and a dry mouth, and pain in one side of your back) – can occur when large amounts of BETADINE® ANTISEPTIC OINTMENT are used.
- Changes in the chemical properties of the blood serum may occur (seen in a test) after

absorption of large amounts of BETADINE® ANTISEPTIC OINTMENT.

- Change in the colour of your skin.

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 SAHPRA website. By reporting side effects, you can help provide more information on the safety of BETADINE® ANTISEPTIC OINTMENT.

## 5. How to store BETADINE® ANTISEPTIC OINTMENT

Store at or below 25 °C.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (i.e. toilets).

## 6. Contents of the pack and other information

**What BETADINE® ANTISEPTIC OINTMENT contains**

Each 1 g of ointment contains povidone-iodine 100 mg (10 % *w/w*), equivalent to 10 mg available iodine.

The other ingredients are macrogol, purified water, sodium bicarbonate.

**What BETADINE® ANTISEPTIC OINTMENT looks like and contents of the pack**

BETADINE® ANTISEPTIC OINTMENT is a smooth uniform dark brown ointment/gel.

BETADINE® ANTISEPTIC OINTMENT is supplied in pre-printed aluminium cylindrical tubes (20 g, 40 g or 100 g) with an internal lacquer lining.

The tube is closed with a polypropylene (PP) or heterophasic copolymer screw cap.

The tubes are enclosed in printed cartons.

Not all pack sizes may be marketed.

**Holder of Certificate of Registration**

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