

BETADINE® Antiseptic Cream

Povidone-Iodine 5%w/w

Consumer Medication Information Leaflet (RiMUP)

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What BETADINE® Cream is used for

- Bacterial and mycotic (fungal) skin infections;
- Bed sore and leg ulcer;
- Minor burns, cuts and abrasions;
- Herpes genitalis.

How BETADINE® Cream works

BETADINE® Cream contains a medicine called Povidone-Iodine. Povidone Iodine has found broad application in medicine as a disinfectant for various purposes.

Before you use BETADINE® Cream

When you must not use it

- If you are allergic to povidone iodine or any ingredients listed;
- If you have a thyroid problem
- If you are to receive or are currently receiving radioactive iodine therapy;
- Newborns and children under 1 year of age;
- If you are using products containing mercury such as thiomersal.

Pregnancy and lactation

Always inform your doctor or pharmacist if you are pregnant or planning a pregnancy, before using **BETADINE®** Cream.

This medicine is not recommended for use in pregnancy or breastfeeding.

Seek medical advice from your doctor or pharmacist.

Before you start to use it

Tell your doctor or pharmacist if you:

- are allergic to iodine or povidone;
- have a thyroid problem;

- are pregnant or planning a pregnancy;
- received radioactive iodine treatments within the last 4 weeks;
- Use for children between 1 to 2 years of age;
- are using **BETADINE®** Cream before any diagnostic test.

Taking other medicines

The concomitant use of other externally applied wound healing medicines/preparations may alter the effect of **BETADINE®** Cream or both. Products containing mercury, enzymatic component, hydrogen peroxide, silver, octenidine and taurolidine may interact with Povidone-Iodine and should not be used concomitantly.

Application of **BETADINE®** Cream may interfere with thyroid function tests.

Do not start a new treatment medication without telling your doctor.

For more information about any other possible risks associated with this medicine, please consult your doctor or pharmacist.

How to use BETADINE® Cream

How much to use

For topical use only.

The cream can be applied once or twice daily, but repeated applications can be done depending on the nature and severity of the condition.

The skin should be cleaned and dried before application.

The affected area may then be covered with a dressing or bandage if required.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

Continue taking **BETADINE®** Cream for as long as your doctor or pharmacist recommends.

If you forget to use it

Use immediately as soon as you remember.

If you use too much (overdose)

Excess iodine can produce goitre and overactive thyroid (hyperthyroidism) or underactive thyroid (hypothyroidism).

In an unlikely event, if you should experience any of the following symptoms: metallic taste in mouth, increased salivation, burning or pain in the throat or mouth, irritation and swelling of the eyes, difficulty in breathing, skin reactions, stomach pain and diarrhoea, any abnormalities due to metabolic disorder, unable to pass urine and kidney failure, immediately consult your doctor.

Therapy: Symptomatic and supportive treatment should be provided with special attention to electrolyte balance and renal and thyroid function.

While you are using it

Things you must do

Use **BETADINE®** Cream exactly as your doctor or pharmacist has told you.

Tell all the doctors and pharmacists treating you that you are using **BETADINE®** Cream.

Tell your doctor immediately if you become pregnant while using this Cream.

Tell your doctor if symptoms do not improve or worsen or you have an allergy or skin irritation such as redness, small blisters, itching, or a rash which may occur immediately.

Things you must not do

Do not use together with alkali, hydrogen peroxide, taurolidine, tannic acid, acetylsalicylic acid, all silver, bismuth and mercury salts.

Things to be careful of

BETADINE® Cream is intended for external use only and not for use on extensive body areas. Application to large areas of broken skin should be avoided as excessive absorption of iodine

may occur. This medication should not be used over a long period of time.

If accidentally swallowed or comes in contact with the eyes, seek medical advice immediately.

Special caution is needed after the end of the treatment to look for the early symptoms of possible overactive thyroid and if necessary the thyroid function should be monitored.

In instances of local irritation or sensitivity, discontinue use.

BETADINE® Cream does not affect your ability to drive or use machinery.

Side effects

Like all medicines, **BETADINE®** Cream can cause side effects, although not everybody gets them.

The side effects such as skin irritation, discolouration, redness, swelling, small blisters, itching, or dry skin, tiredness, weakness, confusion, rapid shallow breathing, passing little or no urine, fluid retention and swelling of legs, ankle and feet.

Visit your doctor or pharmacist immediately if you experience any side effects as listed below after using:

- Allergic 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 or throat – seek medical help straight away.

- Symptoms of a thyroid problem may include feeling nervous, moody, difficulty sleeping, hand tremors, fast or irregular heartbeat, trouble breathing, feeling very hot or sweaty, weight loss, weight gain and tiredness.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of **BETADINE®** Cream

Storage

Store below 30°C.

Keep out of the reach of children.

Jauhi daripada kanak-kanak.

Disposal

Ask your pharmacist how to dispose of used Cream.

Product Description

What it looks like

BETADINE® Cream is a reddish-brown viscous cream.

BETADINE® is a Registered Trademark of iNova Pharma SG Pte Ltd.

Ingredients

- Active ingredient
Povidone-Iodine 5% w/w
- Inactive ingredients
Cetostearyl Alcohol
White Soft Paraffin
Sodium Hydroxide
Paraffin, Liquid
Glycerin/Glycerol/Glycerolum
Macrogol Stearate
Polysorbate 60
Potassium Iodate
Water, Purified
Sorbitan Monostearate

MAL number

MAL14035052XCZ

Manufacturer

Mundipharma Pharmaceutical Ltd
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Product Registration Holder

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Date of revision

6th Mac 2025