

BETADINE® PVP-I Antiseptic Liquid 10%w/v

Povidone-Iodine 10%w/v

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What BETADINE® PVPI Antiseptic Liquid 10%w/v is used for

- Cuts and bruises
- Wounds and burns
- Bacterial and mycotic (fungal) skin infections eg. at groins, feet
- Cold sores
- Herpes simplex, Herpes genitalis
- Disinfection of perineal wounds and skin
- Pre and post-operative disinfection and prepping of the skin.

How BETADINE® PVPI Antiseptic Liquid 10%w/v works

BETADINE® PVPI Antiseptic Liquid 10%w/v is broad-spectrum antiseptic which contains a medicine called Povidone-Iodine that rapidly kills all classes of pathogenic and potentially pathogenic microorganism including protozoa, spores and viruses, fungi or yeast, gram positive and gram negative bacteria. It is virtually non-irritating to the skin and mucosa. It does not stain fabrics and is effective even in presence of blood, pus or necrotic tissue.

Before you use BETADINE® PVPI Antiseptic Liquid 10%w/v

- When you must not use it

- If you are allergic to iodine or povidone or other ingredients listed;
- If you have a thyroid problem;
- If you are to receive or are currently receiving radioactive iodine treatments;
- In 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® PVPI Antiseptic Liquid 10%w/v.

This medicine should not be used regularly during pregnancy unless there is no alternative treatment available.

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

- Taking other medicines

Use of BETADINE® PVPI Antiseptic Liquid 10%w/v should be avoided if you are on concurrent lithium therapy.

Absorption of iodine from povidone iodine through either intact skin or broken skin may interfere with thyroid function tests. Contamination with povidone iodine of several types of tests for the detection of occult blood in faeces or blood in urine may produce false-positive results.

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.

Other antiseptics or medications can affect how BETADINE® works. Avoid preparations containing hydrogen peroxide, silver, tauridine or octenidine.

Tell your doctor if you are using BETADINE® before any diagnostic test.

How to use BETADINE® PVPI Antiseptic Liquid 10%w/v

- How much to use

Apply undiluted to wounds, burns, cuts and bruises or areas infected by bacteria or fungi. Apply a few times a day.

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 using BETADINE® PVPI Antiseptic Liquid 10%w/v for as long as your doctor or pharmacist recommends.

- If you forget to use it

Use immediately as soon as you remember. If it is almost time for the next dose, skip the dose missed and apply only the next regular scheduled dose as instructed.

- 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.

BETADINE® PVP-I Antiseptic Liquid 10%w/v

Povidone-Iodine 10%w/v

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® PVPI Antiseptic Liquid 10%w/v exactly as your doctor or pharmacist has told you.

Tell all the doctors and pharmacists treating you that you are using BETADINE® PVPI Antiseptic Liquid 10%w/v.

Tell your doctor immediately if you become pregnant while using this PVPI Antiseptic Liquid.

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, octenidine and mercury salts.

- Things to be careful of

BETADINE® PVPI Antiseptic Liquid 10%w/v 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.

Use of this preparation may interfere with tests of thyroid function. If symptoms occur suggesting changes in thyroid function, these should be investigated. In patients with impaired kidney function, blood levels of iodine should be monitored.

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

BETADINE® PVPI Antiseptic Liquid 10%w/v does not affect your ability to

drive or use machinery.

Side effects

Like all medicines, BETADINE® PVPI Antiseptic Liquid 10%w/v 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 npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of BETADINE® PVPI Antiseptic Liquid 10%w/v

- Storage

Store at or below 30°C and in cool, dry place protected from light. Discard 6 months after opening.

Keep out of the reach of children. Jauhi daripada kanak-kanak.

- Disposal

Ask your pharmacist how to dispose of used BETADINE® PVPI Antiseptic Liquid 10%w/v.

Product Description

- What it looks like

BETADINE® PVPI Antiseptic Liquid 10%w/v is an reddish-brown, clear solution.

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

- Ingredients

- Active ingredient

Povidone-Iodine 10% w/v

- Inactive ingredients

Macrogol lauryl ether (Laureth-9), Disodium phosphate anhydrous, Citric Acid Monohydrate, Sodium Hydroxide, Potassium Iodate, Purified Water, Glycerol.

- MAL number:

MAL17085001XCZ

Manufacturer

Mundipharma Pharmaceuticals Ltd
13-15, Othellos Street,
Dhali Industrial Area,
2540 Nicosia- Cyprus.

Product Registration Holder

iNova Pharmaceuticals (Singapore) Pte Ltd (incorporated In Singapore)
Malaysia Branch
No. 5F-2, 5th Floor, Tower 2 @PFCC,
Jalan Puteri 1/2, Bandar Puteri, 47100
Puchong, Selangor, Malaysia

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