

BETADINE® Dry Powder Spray

Consumer Medication Information Leaflet (RiMUP)

Povidone-Iodine 2.5%w/w

What is in this leaflet

1. What **BETADINE®** Dry Powder Spray is used for
2. How **BETADINE®** Dry Powder Spray works
3. Before you use **BETADINE®** Dry Powder Spray
4. How to use **BETADINE®** Dry Powder Spray
5. While you are using it
6. Side effects
7. Storage and Disposal of **BETADINE®** Dry Powder Spray
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What **BETADINE®** Dry Powder Spray is used for

- treatment and prevention of skin infections in wounds including ulcers, burns, cuts, abrasions and other minor injuries.

How **BETADINE®** Dry Powder Spray works

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

Before you use **BETADINE®** Dry Powder Spray

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 currently receiving radioactive iodine therapy;
- If you are using products containing mercury such as thiomersal;
- In children under 1 year of age.

Pregnancy and lactation

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

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;
- have kidney failure;
- 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®** Dry Powder Spray before any diagnostic test.

Taking other medicines

The concomitant use of other externally applied wound healing medicines/preparations may alter the effect of **BETADINE®** Dry Powder Spray 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®** Dry Powder Spray 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®** Dry Powder Spray

How much to use

For topical use only.

For adults and children 2 years of age and older

Shake well before use **BETADINE®** Dry Powder Spray. Spray from a distance of 6-10 inches onto the areas to be treated. A thin layer of dust is formed, if necessary cover with a dressing. The dry powder can be applied several times a day (every 3-4 hours).

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®** Dry Powder Spray 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)

In an unlikely event, if you should experience any of the following symptoms: abdominal pain, failure of kidney to produce urine, problem in blood circulation, suffocation, fluid accumulation in the lung and any abnormalities due to metabolic disorder, immediately consult your doctor.

Therapy: Symptomatic and supportive treatment should be provided.

While you are using it

Things you must do

Use **BETADINE®** Dry Powder Spray exactly as your doctor or pharmacist has told you.

Tell all the doctors and pharmacists treating you that you are using **BETADINE®** Dry Powder Spray.

Tell your doctor immediately if you become pregnant while using this Dry Powder Spray.

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® Dry Powder Spray is intended for external use only and not for use on extensive body areas. Do not use on thin lining membrane that covering the organs that lie within that cavity. 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. It will cause allergy or skin inflammation or in rare cases, severe skin reactions.

Avoid solutions containing a detergent if treating open wounds with povidone-iodine.

If accidentally inhaled 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® Dry Powder Spray does not affect your ability to drive or use machinery.

Side effects

Like all medicines, **BETADINE®** Dry Powder Spray 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®

Dry Powder Spray

Storage

Store below 30°C.

Protect from sunlight the pressured container and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even when empty. Do not spray on a naked flame or on any incandescent material.



Pressurized container: Contains highly flammable liquid. Keep away from heat, hot surface sparks or open flames. Do not pierce or burn the can even when empty.

Keep out of the reach of children.

Jauhi daripada kanak-kanak.

Disposal

Ask your pharmacist how to dispose of used spray.

Product Description

What it looks like

BETADINE® Dry Powder Spray is a dry powder pressurized aerosol spray.

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Ingredients

- Active ingredient
Povidone-Iodine 2.5% w/w
- Inactive ingredients
Isopropyl Myristate, N-pentane, Propane + Butane + Isobutane

MAL number

MAL14055180XCZ

Manufacturer

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

Product Registration Holder

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