

PATIENT INFORMATION LEAFLET

BETADINE OINTMENT 5% (Povidone-Iodine Ointment USP)

Povidone-Iodine 5% w/w (available Iodine 0.5% w/w)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Betadine Ointment 5% is and what it is used for
2. Before you use Betadine Ointment 5%
3. How to use Betadine Ointment 5%
4. Possible side effects
5. How to store Betadine Ointment 5%
6. Further information

1. WHAT BETADINE OINTMENT 5% IS AND WHAT IT IS USED FOR

Betadine Ointment 5% is a topical microbicidal ointment used for the treatment and prevention of infections in cuts, wounds, abrasions, surgical incisions and burns. For the treatment of bacterial, viral, and fungal skin infections, decubitus or stasis ulcers, pyodermas and infected traumatic lesions.

2. BEFORE YOU USE BETADINE OINTMENT 5%

Do not use Betadine Ointment 5%

- if you are allergic (hypersensitive) to Iodine or Povidone or any of the other ingredients of Betadine Ointment 5%.
- in abnormal thyroid function.

Warnings

Betadine ointment 5% is used for external use only. If local irritation, redness or swelling develops, discontinue the treatment.

Precautions

Use with caution in patients with renal impairment or electrolyte imbalance. Prolonged use should be avoided.

Pregnancy and breast-feeding

Betadine Ointment 5% should not be used during pregnancy or breast feeding without prior consultation with the doctor.

Further information

Betadine Ointment 5% is fungicidal, trichomonacidal and bactericidal to the pathogenic organisms. In the presence of blood, serum and necrotic tissue, its activity persists. The preparation is water-soluble and does not stain the skin and the golden-brown colouration is easily removed by washing.

3. HOW TO USE BETADINE OINTMENT 5%

• FOR EXTERNAL USE ONLY

The affected area should be cleaned. Betadine Ointment 5% should be applied liberally. The area may be covered with a dressing or a bandage. Betadine Ointment 5% may be used as often as dressing required.

If you use more Betadine Ointment 5% than you should

In case of overdose, acute iodine toxicity is manifested by abdominal symptoms, anuria, circulatory failure, oedema of the glottis resulting in asphyxia, or pulmonary oedema and metabolic abnormalities.

Treatment is symptomatic and supportive.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Betadine Ointment 5% can cause side effects, although not everybody gets them.

Hypersensitive skin reactions may occur (e.g., delayed contact- allergic reactions, which can appear in the form of itching, redness, small blisters or similar manifestations). The long-term use of Povidone-Iodine solution for the treatment of wounds and burns over extensive areas of the skin can lead to a notable uptake of iodine. This should be kept in mind while using Betadine Ointment as well. In isolated cases, patients with a history of thyroid disease can develop hyperfunction of the thyroid (iodine induced hyperthyroidism), sometimes with symptoms such as racing pulse or a feeling of unrest.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider.

5. HOW TO STORE BETADINE OINTMENT 5%

Keep out of the reach and sight of children.

Store protected from light at a temperature not exceeding 30°C. Do not freeze.

Do not use Betadine Ointment 5% after the expiry date which is stated on the label/carton or bottle.

Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how to dispose off medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Betadine Ointment 5% contains

The active substance is Povidone-Iodine USP 5% w/w (Available Iodine 0.5% w/w).

The other ingredients are Polyethylene Glycol 400 USP, Polyethylene Glycol 3350 USP, Sodium bicarbonate BP and Purified water BP.

What Betadine Ointment 5% looks like and contents of the pack

Betadine Ointment 5% is a dark brown smooth ointment, free from any foreign matter.

Betadine Ointment 5% is available in the following packs :

- a) Tube of 15 g enclosed in a carton with pack insert.
- b) Tube of 125 g enclosed in a carton with pack insert.
- c) Jar of 250 g

Registration number of Betadine Ointment 5% is Rwanda FDA-HMP-MA-1365.

Market Authorization Holder

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For any information about this medicinal product, please contact the local representative of the supplier as mentioned below:

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