

PACKAGE LEAFLET: Information for the user

BETADYNE

Solution for local use– 100 mg / ml

(Povidone iodine)

Read 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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness 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 or pharmacist.

In this leaflet:

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

1. WHAT BETADYNE IS AND WHAT IT IS USED FOR

Betadyne contains the active substance povidone iodine. Povidone iodine is a complex of iodine with povidone (polyvinylpyrrolidone), while povidone is a synthetic hydrophilic polymer that plays the role of iodine carrier. This polymer does not have antibacterial effect, but has a great affinity for the cell membrane, while in the form of iodine complex, thus in the form of povidone iodine, releases free iodine directly into the surface of the bacterial cell. The release of iodine from the povidone iodine complex into the bacterial membrane is of essential importance for the iodine action. In the presence of free iodine, sulfhydryl groups, peptides, proteins, hormones, enzymes, lipids and cytosine become iodinated or halogenated and oxidised, which causes the

deactivation of the molecules necessary for the regeneration of the organism. Povidone iodine which is present in the solution 10% measurably maintains its action also in the presence of organic matter, blood, pus, serum and lipids. The action of povidone iodine is quite rapid after the use of the solution and lasts longer than the usual iodine alcoholic solution. After the application of povidone iodine solution, the skin gets a dark colour, which can be easily washed with water.

Betadyne is indicated in:

- preparation of skin and mucous membranes (including vagina) for surgical interventions and injections;
- disinfection of wounds;
- quick treatment of scratches, lacerations, burns (including second and third degree burns);
- local use in candidosis, trichomoniasis and non-specific vaginitis;
- the treatment of oral candidosis as well.

2. BEFORE YOU USE BETADYNE

Do not use Betadyne if you:

- have a known hypersensitivity to iodine, although sensitive persons do not normally react to povidone iodine;
- have thyroid gland disorders;
- are in a concurrent lithium therapy;
- suffer from Duhring's disease (dermatitis herpetiformis);
- are having or just had a radioiodine therapy.

Betadyne should not be used in children younger than 6 months.

Take special care with Betadyne

- in cases of damaged skin;
- when you have thyroid gland disorders;
- when you have impaired renal function;

- when there is a frequent and long-term use of povidone iodine solution, because a pronounced iodine absorption can occur, so that a significant amount of iodine and iodine associated with plasma proteins can be found in the serum; thyroid function tests may be advisable especially in children and persons with thyroid gland disorders;
- when conception is desirable because povidone iodine is spermicide.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Betadyne.

Please inform your doctor or pharmacist if you are taking / using or have recently taken / used other medicines, including those without prescription.

Do not forget to inform your doctor for the treatment with Betadyne if you receive any other medicine during treatment.

It is of the greatest importance that the doctor is aware that you are being treated with other medicines:

- concomitant treatment with lithium may exhibit additive hypothyroidic effects;
- concomitant use of silver sulfadiazine or chlorhexidine may cause deactivation;
- iodine absorbed through undamaged or damaged skin as well as through mucous membranes may interfere with the thyroid function tests;
- it is not recommended to use concomitantly povidone iodine and disinfectant solutions containing mercury salts, hydrogen peroxide, taurolidine or alkalis.

Pregnancy

Ask your doctor or pharmacist for advice before using this medicine during pregnancy because its use is not recommended.

Breastfeeding

Ask your doctor or pharmacist for advice before using this medicine during breastfeeding because its use is not recommended.

3. HOW TO USE BETADYNE

The solution is applied directly on the affected areas of the skin 3 times daily or it is used in the form of compresses in the wounds.

If it is going to be used for other indications, the solution should be diluted in advance.

If you use more Betadyne than you should

If you use more Betadyne than you should, or if the children have taken it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures to be taken.

If you forget to use Betadyne

If you forget one dose (or more), use the next dose in its usual time.

Do not use a double dose (or higher) to make up the forgotten dose (doses). If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Betadyne can cause side effects, although not everybody gets them.

Sometimes they are serious, most of the time not. Do not get alarmed by this list of possible side effects. You may not get any of them.

The most frequent side effects are:

- hypersensitivity reactions that appear with irritation of the skin and mucous membranes, with redness and itching of the area where it is used;
- hyperthyroidism and hypothyroidism may appear after the absorption of large quantities of povidone iodine;
- povidone iodine use on large areas of damaged skin (wounds or severe burns) may cause systemic side effects, such as: metabolic acidosis, hyponatremia, renal function impairment, convulsions and neutropenia;
- anaphylactic reaction after the vaginal use of povidone iodine solution.

If any of the side effects gets worse, or you get any side effects not listed in this leaflet, please talk to your doctor or pharmacist.

5. HOW TO STORE BETADYNE

Keep out of the reach and sight of children.

Do not use Betadyne after the expiry date which is stated on the package.

Do not store above 25°C.

Keep in the original package.

6. OTHER INFORMATION

What Betadyne contains:

The active substance is povidone iodine.

1 ml solution contains 100 mg of povidone iodine.

The other ingredients are: povidone, citric acid monohydrate, disodium hydrogen phosphate dihydrate, ethanol, purified water.

Content of the pack

Carton box with one plastic bottle 100 ml.

Plastic bottle 1000 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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