

PATIENT INFORMATION LEAFLET

BETADINE GERMICIDE GARGLE 2%-MINT

(Povidone-Iodine Gargle)

Povidone-Iodine 2% w/v (available Iodine 0.2% w/v)

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 Germicide Gargle 2%-Mint is and what it is used for
2. Before you use Betadine Germicide Gargle 2%-Mint
3. How to use Betadine Germicide Gargle 2%-Mint
4. Possible side effects
5. How to store Betadine Germicide Gargle 2%-Mint
6. Further information

1. WHAT BETADINE GERMICIDE GARGLE 2%-MINT IS AND WHAT IT IS USED FOR

Betadine Germicide Gargle 2%-Mint is a germicide gargle and is used as a gargle or mouthwash as primary or adjunctive therapy in infections of the mouth and throat such as aphthous ulcers, stomatitis, Vincent's infection, pharyngitis, oral moniliasis, tonsillitis and following oral surgery and dental procedures. As a mouth wash for routine use. Betadine Germicide Gargle 2%-Mint eliminates or reduces offensive mouth odours.

2. BEFORE YOU USE BETADINE GERMICIDE GARGLE 2%-MINT

Do not use Betadine Germicide Gargle 2%-Mint

- if you are allergic (hypersensitive) to Iodine or Povidone or any of the other ingredients of Betadine Germicide Gargle 2%-Mint.
- in hyperfunction of the thyroid (hyperthyroidism), other manifest thyroid diseases, as well as before and after radioactive iodine therapy. It should not be used prior to radioiodine scintigraphy or radioiodine treatment of thyroid carcinoma.

Pregnancy and breast-feeding

During pregnancy and lactation, povidone-iodine should only be used, if strictly indicated and its use should be kept to the absolute minimum. (Because of the ability of iodine to pass through the placenta and be secreted in breast milk, and because of the increased sensitivity of the foetus and newborn to iodine, no large amounts of povidone-

iodine should be administered during pregnancy and lactation. Povidone-Iodine use may induce transient hypothyroidism with elevation of TSH in the foetus or in the newborn. A check of the child's thyroid function may be necessary. Any possible oral ingestion of the solution by the infant/child must be absolutely avoided.

Interactions

The PVP-iodine complex is effective at pH values of between 2.0 and 7.0. It has to be expected that the complex will react with protein and other unsaturated organic compounds, leading to Impairment of its effectiveness. The concomitant use of wound-treatment preparations containing enzymatic components leads to weakening of the effects of both substances. Products containing mercury, silver, hydrogen peroxide, and tauridine may interact with povidone-iodine and should not be used concomitantly.

3. HOW TO USE BETADINE GERMICIDE GARGLE 2%-MINT

• FOR EXTERNAL USE ONLY

Adults & Children : Dilute Betadine Germicide Gargle 2% Mint with an equal volume of water and gargle or rinse for 30 seconds. Repeat every two to four hours for as long as required.

For gargle or mouth wash: Dilute Betadine Germicide Gargle 2% Mint with an equal volume of water and rinse or gargle for 30 seconds and then spit out, repeat hourly or as directed by physician.

As a routine mouthwash : Effective up to dilution of one part Betadine Germicide Gargle 2% Mint with two parts of water, rinse mouth thoroughly & spit out, or as directed by physician or dentist.

If you use more Betadine Germicide Gargle 2%-Mint than you should

Acute iodine toxicity is manifested by abdominal symptoms, anuria, circulatory collapse, laryngeal edema resulting in asphyxia, or pulmonary edema and metabolic abnormalities.

Treatment is symptomatic and supportive.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Betadine Germicide Gargle 2%-Mint can cause side effects, although not everybody gets them.

Hypersensitive skin reactions may occur (e.g., delayed contact-allergic reactions).

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 GERMICIDE GARGLE 2%-MINT

Keep all medicines out of the reach and sight of children.

Store protected from light at a temperature not exceeding 30°C. Replace the cap tightly after use.

Do not use Betadine Germicide Gargle 2%-Mint after the expiry date which is stated on the label/carton.

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 Germicide Gargle 2%-Mint contains

The active substance is Povidone-Iodine USP 2% w/v (Available Iodine 0.2% w/v). Betadine Germicide Gargle 2% -Mint also contains : Absolute alcohol content is 8.38% v/v.

The other ingredients are Menthol USP, Methyl Salicylate BP, Glycerin BP, Saccharin Sodium BP, Purified Water BP, Absolute alcohol.

What Betadine Germicide Gargle 2%-Mint looks like and contents of the pack

Betadine Germicide Gargle 2%-Mint is clear dark brown coloured liquid with characteristic odour.

Betadine Germicide Gargle 2%-Mint is available in the following packs :

- a) Amber coloured PET bottle of 50 ml enclosed in carton with pack insert.
- b) Amber coloured PET bottle of 100 ml enclosed in carton with pack insert.

Registration number of Betadine Germicide Gargle 2%-Mint is Rwanda FDA-HMP-MA-1382.

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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