

POVIDONE-IODINE

BETADINE®

Read this leaflet carefully before you start using this product.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

1. NAME OF THE PRODUCT

POVIDONE-IODINE (BETADINE®) 4.5mg/mL (0.45% w/v) oromucosal solution (throat spray)

2. DESCRIPTION OF THE PRODUCT

POVIDONE-IODINE (BETADINE®) throat spray is an oral solution. It is a smooth yellowish-brown liquid available in 50mL container.

3. WHAT IS IN THE POVIDONE-IODINE (BETADINE®) THROAT SPRAY?

POVIDONE-IODINE (BETADINE®) throat spray is a powerful antiseptic scientifically proven to eliminate numerous types of harmful microorganisms like bacteria, viruses and fungi.

POVIDONE-IODINE (BETADINE®) throat spray contains the broad spectrum antiseptic povidone-iodine which retains all the advantages of elemental iodine without staining or sensitizing.

4. STRENGTH OF THE POVIDONE-IODINE (BETADINE®) THROAT SPRAY

Each mL contains:

Povidone-Iodine, EP..... 4.5mg
(equivalent to 0.45 mg available iodine)

5. WHAT IS THE POVIDONE-IODINE (BETADINE®) THROAT SPRAY USED FOR?

POVIDONE-IODINE (BETADINE®) throat spray is indicated for the treatment of acute mucosal infections of the mouth and pharynx including stomatitis, gingivitis, aphthous ulcers, pharyngitis, tonsillitis, monilial infections, common colds and influenza.

For oral hygiene prior to, during and after dental and oral surgery.

For fast and soothing relief of sore throat.

6. HOW MUCH AND HOW OFTEN SHOULD YOU USE POVIDONE-IODINE (BETADINE®) THROAT SPRAY?

Spray to the mucous membrane of the throat several times a day (every 3-4 hours) or as directed by your doctor.

7. WHEN SHOULD YOU NOT USE POVIDONE-IODINE (BETADINE®) THROAT SPRAY?

POVIDONE-IODINE (BETADINE®) throat spray should not be used:

- If you are allergic to iodine or povidone
- If you have an overactive thyroid gland (hyperthyroidism) or any thyroid diseases, as well as before and after radioiodine therapy for hyperthyroidism, until a lasting cure has been obtained
- Not be used for 4 weeks prior to radioiodine scintigraphy or radioiodine treatment of thyroid carcinoma
- If you have goiter, thyroid nodules, or other thyroid diseases
- If you are on lithium therapy
- Before and after a specific medical treatment involving the use of radioactive iodine

If you feel you have experienced an allergic reaction, stop using **POVIDONE-IODINE (BETADINE®)** throat spray and inform your doctor or pharmacist immediately.

Not to be used in children below 6 years old.

8. CARE THAT SHOULD BE TAKEN WHEN TAKING POVIDONE-IODINE (BETADINE®) THROAT SPRAY

Using this treatment may interfere with tests on thyroid function and can make a planned treatment of the thyroid with iodine impossible. After the end of the treatment an interval of at least 1-2 weeks should be allowed before a new scintigram is carried out.

Keep out of reach of children.

Do not heat **POVIDONE-IODINE (BETADINE®)** throat spray prior to use.

Avoid getting **POVIDONE-IODINE (BETADINE®)** throat spray in your eyes. Avoid solutions containing a detergent if treating open wounds with povidone-iodine.

Patients with goiter, thyroid nodules or other non-acute thyroid diseases are at risk of developing thyroid hyperfunction (hyperthyroidism) from the administration of large amounts of iodine. In this patient population, povidone-iodine should not be applied for an extended period of time unless strictly indicated. Even after the end of the treatment, one should look for the early symptoms of possible hyperthyroidism and if necessary the thyroid function should be monitored.

It should not be used prior to or after radioiodine scintigraphy or radioiodine treatment of thyroid carcinoma.

Newborns and small infants are at increased risk of developing hypothyroidism from the administration of large amounts of iodine. Because of the permeable nature of the skin and their increased sensitivity to iodine, the use of povidone-iodine should be kept to the absolute minimum in newborns and small infants. A check of their thyroid function (e.g. T₄ levels and TSH levels) may be necessary.

In oropharyngeal use precautions should be taken to prevent aspiration of **POVIDONE-IODINE (BETADINE®)** throat spray into the respiratory tract as this may cause complications such as pneumonitis. This may particularly occur in intubated patients.

Avoid use in patients with renal impairment.

If symptoms persist, consult your doctor.

Pregnancy and Lactation

During pregnancy and lactation, **POVIDONE-IODINE (BETADINE®)** throat spray should only be used if strictly prescribed by the doctor and its use should be kept to the absolute minimum. Seek medical advice from your doctor or pharmacist. 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 fetus and newborn to iodine, no large amounts of povidone-iodine should be administered during pregnancy and lactation. Moreover, iodine is concentrated in the breast milk, as compared with the serum. **POVIDONE-IODINE (BETADINE®)** use may induce transient hypothyroidism with elevation of TSH (thyroid stimulating hormone) in the fetus or in the newborn. A check of the newborn's thyroid function may be necessary. Any oral ingestion of the solution by the newborn or infant must be avoided

9. UNDESIRABLE EFFECTS OF POVIDONE-IODINE (BETADINE®) THROAT SPRAY

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

The side effects listed below may not include all of the side effects reported. For more information about any other possible risks associated with **POVIDONE-IODINE (BETADINE®)** throat spray, please consult your doctor or pharmacist.

Please note that the side effects related to the use of POVIDONE-IODINE (BETADINE®) throat spray occur rarely.

Rarely, hypersensitive/allergic skin reaction may occur, which can appear in the form of:

- itchiness
- redness
- small blisters
- contact dermatitis (with symptoms such as erythema, small blisters and pruritus)

Very rarely, acute generalized allergic reactions have been reported with

- drop in blood pressure
- difficulty in breathing
- swelling of the skin and mucosa
- anaphylactic reaction
- hyperthyroidism (sometimes with symptoms such as tachycardia or restlessness)
- angioedema

Not known

- hypothyroidism
- electrolyte imbalance
- metabolic acidosis
- pneumonitis
- dermatitis exfoliative
- dry skin

- acute renal failure
- blood osmolarity abnormal
- chemical burn of skin
- thermal burn

If you notice any side effects, please consult your doctor or pharmacist.

The long term use of the product, not in accordance with the usage instructions mentioned under section 6, may lead to possible absorption of iodine into the body. This may lead to

- overactive thyroid gland function if you have a history of thyroid problems, rapid heartbeat (tachycardia) and restlessness
- imbalance of electrolytes
- abnormal blood concentration (osmolarity)
- abnormal kidney function (renal impairment)

10. WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING POVIDONE-IODINE (BETADINE®) THROAT SPRAY?

Do not apply other medications to the same affected areas you treat with **POVIDONE-IODINE (BETADINE®)** throat spray, unless your doctor has told you so.

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.

It is not likely that other drugs you take orally or inject will have an effect on **POVIDONE-IODINE (BETADINE®)** throat spray.

Povidone-iodine products when used concomitantly or immediately after application of octenidine containing antiseptics in the same or adjacent sites may lead to transient dark discolorations in the areas involved.

Due to the oxidative effect of povidone-iodine preparations various diagnostic agents can show false-positive lab results (e.g., tests with toluidine or gum guaiac for the determination of hemoglobin or glucose in the stool or the urine).

Absorption of iodine from povidone-iodine solution may lower the iodine uptake of the thyroid. This can lead to interference with various investigations (thyroid scintigraphy, determination of PBI (protein-bound iodine), radioiodine diagnostics and can make a planned treatment of the thyroid with iodine (radioiodine therapy) impossible. After the end of the treatment, an appropriate interval should be allowed before a new scintigram is carried out.

Do not start a new treatment medication without telling your doctor.

For more information about any other possible risks associated with **POVIDONE-IODINE (BETADINE®)** throat spray, please consult your doctor or pharmacist.

11. WHAT SHOULD YOU DO IF YOU MISS A DOSE?

Follow the usage instructions mentioned in section 6. If you miss a treatment, use it as soon as you remember. For more information, please consult your doctor or pharmacist.

12. SIGNS & SYMPTOMS OF OVERDOSE

In the unlikely event of deliberate or accidental ingestion of large quantities of povidone-iodine acute iodine toxicity is experienced with any of the following symptoms: stomach pain, unable to pass urine, circulatory failure, edema of glottis resulting asphyxia, pulmonary edema, metabolic abnormalities, loss of appetite, weakness, nausea and vomiting, coughing up blood, excessive sweating, difficulty in breathing, metabolic acidosis, anxiety and pale skin, immediately consult your doctor.

Treatment is symptomatic and supportive.

13. WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

Please consult your doctor or pharmacist.

14. HOW SHOULD YOU KEEP POVIDONE-IODINE (BETADINE®) THROAT SPRAY?

Do not use **POVIDONE-IODINE (BETADINE®)** throat spray after the expiry date indicated on the label.

Store at temperatures not exceeding 30°C.

15. WHEN SHOULD YOU CONSULT YOUR DOCTOR?

In case of allergic symptoms, stop treatment and consult your doctor.

Call your doctor if your symptoms do not improve or if they get worse. Also call your doctor if your symptoms had cleared up but reappeared again.

If you experience any side effect/s or adverse drug reaction/s with the use of this product, immediately seek medical attention and report via FDA at www.fda.gov.ph and Mundipharma Drug Safety Unit at DrugSafety@mundipharma.com.ph/+639175696653.

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