PROFESSIONAL INFORMATION

SCHEDULING STATUS **S0**

1 NAME OF THE MEDICINE

BETADINE® THROAT SPRAY 0,45 % *w/v* (Solution)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 4,5 mg povidone-iodine (0,45 % *w/v*).

Excipients with known effect:

BETADINE® THROAT SPRAY contains 20 % *w/v* ethanol (alcohol)

For the full list of excipients, see section 6.1.

BETADINE® THROAT SPRAY is sugar free.

3 PHARMACEUTICAL FORM

Solution (Oromucosal spray), which is pale-brown, slightly viscous and presents with a distinctive perfume and sweet taste

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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.
- oral hygiene prior, during and after dental and oral surgery, e.g. after tonsillectomy and dental procedures.

4.2 Posology and method of administration

Posology

For oromucosal use only.

Paediatric Population

Not to be used in children below 6 years of age.

Method of administration

Adult and children aged 6 years and above: one spray onto the back of the throat or affected area every 3 – 4 hours as needed, up to 3 sprays per day for a maximum of 7 days.

1. Remove the cap from the nozzle.

2. Please note that the pump has to be completely pushed down before spraying.

3. Tilt your head back slightly, open your mouth and aim the nozzle towards the back of the throat.

4. Hold your breath and press the pump down to spray. Do not breathe in the spray.

5. Wipe the nozzle and place the cap back after use.

4.3 Contraindications

- Hypersensitivity to iodine or povidone or to any of the excipients listed in section 6.1.
- Not to be used in hyperfunction of the thyroid (hyperthyroidism) or other manifest thyroid diseases.
- Not to be used in patients on concurrent lithium therapy.
- Children under 6 years of age.

4.4 Special warnings and precautions for use

Patients with goiter, thyroid nodules, or other non-acute thyroid diseases are at risk of developing hyperthyroidism from the administration of large amounts of iodine. In this patient population povidone-iodine should not be used for an extended period of time (e.g., for no longer than 14 days) unless strictly indicated. Even after the end of the treatment (up to 3 months), 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 radioidine treatment of thyroid carcinoma.

In oropharyngeal use, precautions should be taken to prevent aspiration of BETADINE® THROAT SPRAY into the respiratory tract as this may cause complications such as pneumonitis. This may particularly occur in intubated patients.

Special caution is needed when regular applications to broken skin are made to patients with pre-existing renal insufficiency.

Newborns and small infants are at increased risk of developing hypothyroidism from the administration of large amounts of iodine. Because of 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 the child's thyroid function (e.g. T_4 levels and TSH levels) may be necessary. Any possible oral ingestion of the product by the infant must be absolutely avoided.

In instances of local irritation or sensitivity, discontinue use.

BETADINE® THROAT SPRAY contains 40 mg of alcohol (ethanol) in each dose (spray). The amount in each dose (spray) of this medicine is equivalent to less than 1 ml of beer or wine. The small amount of alcohol in BETADINE® THROAT SPRAY will not have any noticeable effects.

Flammable, contains alcohol: keep away from open flames or heat.

Do not heat prior to application.

For mouth and throat only.

4.5 Interaction with other medicines and other forms of interaction

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.

Use should be avoided in patients receiving concomitant lithium therapy (see Section 4.3).

The concomitant use of wound-treatment preparations containing enzymatic components leads to a weakening of the effects of both substances. Products containing mercury, silver, hydrogen peroxide and taurolidine may interact with povidone-iodine and should not be used

concomitantly. Simultaneous use with mercury products may lead to the formation of a substance, which can damage the skin.

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.

Absorption of iodine from BETADINE® THROAT SPRAY may interfere with thyroid function tests or radioiodine therapy. During the use of BETADINE® THROAT SPRAY the iodine uptake of the thyroid can be lowered; 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.

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

4.6 Fertility, pregnancy and lactation

During pregnancy and lactation, BETADINE® THROAT SPRAY, 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 BETADINE® THROAT SPRAY should be administered during pregnancy and lactation. Moreover, iodine is concentrated in the breast milk, as compared with the serum. Povidone-iodine use may induce transient hypothyroidism with elevation of TSH (thyroid stimulating hormone) in the foetus or in the newborn. A check of the newborn's thyroid function may be necessary, especially in areas known for endemic low dietary iodine and high prevalence of goitre.

Any oral ingestion of the solution by the newborn or infant must be avoided.

Fertility

No data is available.

4.7 Effects on ability to drive and use machines

BETADINE® THROAT SPRAY has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders

Less frequent: Hypersensitivity, anaphylactic reaction

Endocrine disorders

Less frequent: Hyperthyroidism (sometimes with symptoms such as tachycardia or restlessness) *

Frequency unknown: Hypothyroidism ****

Metabolism and nutrition disorders

Frequency unknown: Electrolyte imbalance **, metabolic acidosis **

Skin and subcutaneous tissue disorders

Less frequent: Contact dermatitis (with symptoms such as urticaria, erythema, small blisters and pruritus), angioedema

Renal and urinary disorders

Frequency unknown: Acute renal failure**, Blood osmolarity abnormal **

Injury, poisoning and procedural complications

Frequency unknown: Chemical burn of skin ***

* In patients with a history of thyroid disease (see Section 4.4) following a notable uptake of iodine e.g. following long term use of povidone–iodine solution for the treatment of wounds and burns over extensive areas of the skin

** May occur following uptake of large amounts of povidone-iodine (e.g. in the treatment of burns)

*** May occur due to “pooling” beneath the patient in pre-operative preparation

**** Hypothyroidism following prolonged or extensive use of povidone-iodine

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

Alternatively report to: ZADrugSafety@mundipharma.co.za

4.9 Overdose

In the case of deliberate or accidental ingestion of large quantities of povidone-iodine acute iodine toxicity is manifested by abdominal symptoms, anuria, circulatory failure, oedema of glottis resulting in asphyxia, or pulmonary oedema and metabolic abnormalities.

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

A. 16.4. Naso-pharyngeal and bucco-pharyngeal antiseptics

5.1 Pharmacodynamic properties

Povidone-iodine is a complex of the polymer polyvinylpyrrolidone with iodine (povidone-iodine) which, after application, continues to deliver iodine over a period of time. Elemental iodine (I_2) has long been known as a highly effective microbicidal agent that rapidly kills bacteria, viruses, fungi and some protozoa *in vitro*. Two mechanisms are involved: free iodine rapidly causes microbial killing, whereas iodine bound to the polymer serves as a reservoir. As the preparation comes in contact with the skin and mucous membranes, more and more iodine dissociates from the polymer. The free iodine reacts with oxidisable –SH or –OH groups of the amino acids in the enzymes and structural proteins of microorganisms thereby inactivating

and killing these enzymes and proteins. Most vegetative microorganisms are killed in less than a minute *in vitro*, with many destroyed within 15 to 30 seconds.

5.2 Pharmacokinetic properties

Absorption

In normal individuals, topical application results in very little systemic iodine absorption.

Elimination

Povidone (PVP)

Absorption and, in particular, renal elimination of povidone depend on the (mean) molecular weight (of the mixture). For molecular weights of more than 35000 to 50000, retention must be expected.

Iodine

The behaviour of absorbed iodine or iodide in the organisms is largely similar to that of iodine taken up by other routes. The volume of distribution corresponds to approximately 38 % of body weight in kg.

Elimination is almost exclusively by renal route with a clearance of 15 to 60 m plasma/min depending on serum iodine level and creatinine clearance.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol, eucalyptus oil, glycerol, levomenthol, potassium iodide, purified water.

6.2 Incompatibilities

BETADINE® THROAT SPRAY should not be used together with alkali, hydrogen peroxide, taurolidine, tannic acid, silver and mercury salts.

6.3 Shelf life

3 years.

Do not use this medicine after the expiry date indicated on the container. The product can be stored for 3 months after opening.

6.4 Special precautions for storage

Store at or below 30 °C.

Flammable. Keep away from open flames or heat.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

Light yellow/cream coloured, cylindrical high density polyethylene (HDPE) container with a white polyethylene/polypropylene spray pump and a transparent polystyrol copolymer cap. One container is packed into a cardboard carton.

Pack sizes: 50ml.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Mundipharma (Pty) Ltd,

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8 REGISTRATION NUMBER

50/16.4/0436

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07 June 2022

10 DATE OF REVISION OF THE TEXT

07 June 2022