PROFESSIONAL INFORMATION

SCHEDULING STATUS **S0**

1 NAME OF THE MEDICINE

BETADINE® ANTISEPTIC OINTMENT 10 % *w/w* (ointment)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of ointment contains povidone-iodine 100 mg (10 % *w/w*), equivalent to 10 mg available iodine.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A smooth uniform dark brown ointment/gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

BETADINE® ANTISEPTIC OINTMENT is indicated for the topical application in the treatment or prevention of infections in minor wounds, cuts, abrasions, burns and ulcers.

4.2 Posology and method of administration

For topical use only.

Posology

A pea sized amount of ointment should be applied to the affected area for 7 to a maximum of 14 consecutive days.

Method of administration

The skin should be cleaned and dried before application.

The amount applied is spread evenly and it depends also upon the size of the area to be treated.

- Children from 2-6 years: up to 2 pea sized amounts a day
- Children up to 7-8 years: up to 3 pea sized amounts a day
- Children from 9-14 years: up to 4 pea sized amounts a day
- Children from 15-18 years: up to 5 pea sized amounts a day
- Adults: 5-6 pea sized amounts a day

If required, a dressing or bandage can be applied afterwards.

Special populations

There is no adjustment of dose required in elderly population.

Paediatric population

Betadine Antiseptic Ointment is contraindicated for use in children below 2 years of age (See section 4.3).

4.3 Contraindications

- Hypersensitivity to iodine or povidone or any other of the excipients listed in section 6.1.
- Thyroid dysfunction.
- During radioiodine scintigraphy or radioiodine treatment of thyroid diseases.
- Products containing mercury, should not be used concomitantly due to formation of a substance which can damage the skin.
- Not to be used in patients on concurrent lithium therapy.
- Children below the age of 2 years.

4.4 Special warnings and precautions for use

- Use of this preparation may interfere with tests of thyroid function. Iodine is absorbed through burns and broken skin and to a lesser extent through intact skin and may lead to toxic levels of iodine in the blood, particularly in patients with renal insufficiency. If symptoms occur suggesting changes in thyroid function, these should be investigated. In patients with impaired renal function, blood levels of iodine should be monitored.
- In pre-operative preparation, avoid pooling beneath the patient. Prolonged exposure to wet solution may cause irritation or rarely, severe skin reactions. Chemical burns of skin due to pooling may occur.
- In instances of skin irritation, contact dermatitis or hypersensitivity, discontinue use.
- Do not heat prior to application.
- Special caution is needed in pregnant and breast-feeding women.
- Povidone iodine use could lead to transient skin discolouration at the application site

Paediatric population

BETADINE® ANTISEPTIC application in children needs to be performed by an adult.

For external use only.

Changes in the international and local antimicrobial resistance patterns should be a consideration. Principles of antibiotics stewardship should be adhered to.

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.

The concomitant use of wound-treatment preparations containing enzymatic components leads to a weakening effect of both substances. Products containing silver and taurolidine may interact with povidone-iodine.

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.

Effects on diagnostic tests

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 haemoglobin or glucose in the stool or the urine).

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

Use should be avoided in patients receiving concomitant lithium therapy , a potential interaction could lead to hypothyroidic effects (see Section 4.3).

4.6 Fertility, pregnancy and lactation

During pregnancy and lactation, BETADINE® ANTISEPTIC OINTMENT should only be used if strictly indicated and its use should be kept to the absolute minimum, since absorbed iodine can pass through the placenta and be secreted in breast milk.

Pregnancy

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 child’s thyroid function may be necessary.

Breastfeeding

Iodine is excreted in breast milk and is present in higher concentrations in the breast milk compared to those in the serum.

Also, any oral ingestion of the cream by the infant must be avoided, therefore, breastfeeding women should ensure they do not apply BETADINE® ANTISEPTIC OINTMENT to the breast when they are breastfeeding.

Fertility

No data is available.

4.7 Effects on ability to drive and use machines

BETADINE® ANTISEPTIC OINTMENT has no influence on the ability to drive and use machines.

4.8 Undesirable effects

The following adverse reactions have been reported with BETADINE® ANTISEPTIC OINTMENT either during clinical trials or during post-marketing experience:

Very common (≥ 1/10), Common (≥ 1/100, < 1/10), Uncommon

(≥ 1/1 000, < 1/100), Rare (≥ 1/10 000, < 1/1 000), Very rare (<1/10 000) and

Not known (cannot be estimated from the available data).

Immune system disorders

Rare: Hypersensitivity

Very rare: Anaphylactic reaction

Endocrine disorders

Very rare: Hyperthyroidism (sometimes with symptoms such as tachycardia or restlessness) *

Not known: Hypothyroidism ***

Metabolism and nutrition disorders

Not known: Electrolyte imbalance **, metabolic acidosis **

Skin and subcutaneous tissue disorders

Rare: Contact dermatitis (with symptoms such as erythema, small blisters and pruritus)

Very rare: Angioedema

Unknown: Skin discolouration

Renal and urinary disorders

Not known: Acute renal failure**, Blood osmolarity abnormal **

* 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)

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

Reporting 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

Systemic absorption of iodine after repeated application of povidone-iodine to large areas of wounds or burns or deliberate or accidental ingestion of large quantities of povidone-iodine may lead to a number of overdose effects.

Systemic toxicity may result in renal impairment (including anuria), metabolic acidosis, acute respiratory distress and congestive heart failure.

In the case of deliberate or accidental ingestion of large quantities of povidone-iodine the following may manifest: oesophagitis, gastritis, chemical pulmonary oedema, transient hyperthyroidism, haemolytic anaemia, acute tubular necrosis and several acid-base disturbances.

Treatment

In the case of deliberate or accidental ingestion of large quantities of BETADINE® ANTISEPTIC OINTMENT, symptomatic and supportive treatment should be provided with special attention to electrolyte balance and renal and thyroid function.

Treatment of toxicity from exposure to excess iodine is directed at lowering exposure and, if clinical hypothyroidism or hyperthyroidism persists, correcting the thyroid dysfunction.

5 PHARMACOLOGICAL PROPERTIES

A.14.1 Antibacterial and antiseptic agents (dermatological)

5.1 Pharmacodynamic properties

Povidone iodine is a complex of iodine (the active moiety) and the synthetic polymer povidone, (PVP), which acts as a sustained release reservoir of iodine (PVP does not have any intrinsic antibacterial activity) and also enables easier contact of iodine to cell membranes.

As povidone iodine comes in contact with the skin and mucous

membranes, iodine dissociates from the povidone iodine polymer complex; it is the free iodine that rapidly causes microbicidal activity, whereas iodine bound to the polymer serves as an iodine reservoir. This gradual release of iodine reduces the drawbacks associated with the presence of elemental iodine and maintains its highly effective microbiocidal activity. The

free iodine rapidly penetrates microorganisms and attacks the key groups of proteins, amino acids, nucleotides and unsaturated fatty acids. It reacts with thiol, sulfhydryl and hydroxyl groups of the amino acids in the enzymes and structural proteins of the microorganisms thereby oxidising them

5.2 Pharmacokinetic properties

Absorption

The pharmacokinetics of povidone iodine are influenced by the dissociation of povidone, (hydrophilic) and iodine (lipophilic) and duration of exposure. Different formulations and different routes of administration would impact the absorption of povidone iodine and the extent of the systemic absorption of each formulation of povidone iodine depends on the localisation and the conditions of its use (area, healthy skin surface, damaged skin surface, mucous membranes, wounds, body cavities) and the duration of application.

Studies *in vivo* indicate that iodine can be absorbed via the skin and the amount absorbed is dependent on the type of skin (e.g., healthy or damaged) and also on the duration and the surface area of the application.

Limited amount of iodine is absorbed through an intact skin (5%); enhanced absorption occurs through denuded skin, damaged skin, or large areas of intact skin. A negligible amount of povidone (~ 35 KDa) could be absorbed into the systemic circulation. Following dissociation of iodine from povidone, the skin absorbs iodine and the amount absorbed is dependent on the type of skin (e.g., healthy or damaged) and also on the duration and the surface area of the application.

5.3 Preclinical safety data

Acute toxicity

In experimental animal investigations (mouse, rat, rabbit, dog), acutely toxic effects were found after systemic administration (oral, i.p., i.v.) only with excessively high doses that are of no significance for the local use of povidone-iodine.

Chronic toxicity

Subchronic and chronic toxicology tests have been performed in rats fed povidone-iodine in dose levels of 75 to 750 mg/kg/day for up to 12 weeks.

Dose dependent and reversible increases in protein-bound iodine and non-specific histopathological changes in the thyroid were observed.

Mutagenic and tumour-inducing potential

No carcinogenicity studies have been conducted; no information is therefore available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol, purified water, sodium bicarbonate.

6.2 Incompatibilities

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

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

BETADINE® ANTISEPTIC OINTMENT is supplied in pre-printed aluminium cylindrical tubes (20 g, 40 g or 100 g) with an internal lacquer lining.

The tube is closed with a polypropylene (PP) or heterophasic copolymer screw cap.

The tubes are enclosed in printed cartons.

Not all pack sizes may be marketed.

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road

Bedfordview, 2007

South Africa

8 REGISTRATION NUMBER

57/13.1/0506

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