Professional Information for Medicines for Human Use

SCHEDULING STATUS: S0

1. NAME OF MEDICINE

BIOCREAM ANTISEPTIC CREAM 5 %

Strength

50 mg of Povidone-Iodine equivalent to 5 mg of available iodine.

Pharmaceutical form

Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of Biocream antiseptic cream 5 % contains 50 mg of Povidone-Iodine equivalent to 5 mg of available iodine.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cream

A brown cream with the characteristics and smell of iodine.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

As an antiseptic for skin infections, burns, cuts, abrasions, wounds, postoperative wounds and decubitus ulcers.

4.2. Posology and method of administration

Clean and dry the affected area. Liberally apply Biocream antiseptic cream 5 % and cover with bandage or dressing. Change dressing daily and reapply Biocream.

4.3. Contraindications

- Sensitivity to Povidone-Iodine or other iodine containing products.
- Thyroid disorders, in particular overactive thyroid (hyperthyroidism), nodular colloid goitre, endemic goitre and Hashimoto's thyroiditis.

4.4. Special warnings and precaution for use

For external use only.

Not to be used by persons allergic to iodine.

Not recommended in pregnant or lactating women.

4.5. Interaction with other medicines and other forms of interaction

Absorption of iodine from povidone-iodine may interfere with thyroid function tests by causing an increase in protein bound iodine levels. Contamination with povidone-iodine of several types of tests for the detection of occult blood in urine may produce false positive results.

4.6. Fertility, pregnancy, and lactation

The safety in fertility, pregnancy and breastfeeding has not been established.

Biocream antiseptic cream 5 % is not recommended in pregnant or breastfeeding women.

4.7. Effects on the ability to drive and use machines

Biocream antiseptic cream 5 % has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

System organ class	Frequency	Undesirable effects
Immune System Disorders	Less Frequency	Hypersensitivity skin irritation, redness swelling
Endocrine disorders	Less frequent	Hypothyroidism Anaphylactic reaction
Metabolism and nutrition disorders	Less frequent	Metabolic acidosis, hypernatraemia
Skin and subcutaneous tissue disorders	Less frequent	Skin reaction localised
Renal and urinary disorders	Frequency not known	Renal impairment

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 provders 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

4.9. Overdose

Metabolic acidosis and renal impairment may occur if applied to large areas or denuded skin.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

13.1 Antiseptics, Disinfectants and Cleansing agents

Mechanism of action

Biocream antiseptic cream 5 % is an iodophor which has the microbiological activity of elemental iodine.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Emulgade A6

Eumulgin B25

Cetyl Steryl Alcohol

Liquid Paraffin

Glycerine

Purified water

6.2. Incompatibilities

Alkali will reduce the anti-microbial activity of povidone-iodine

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store at or below 25 °C.

6.5. Nature and contents of container

25 g LDPE tubes and closed with a cap

500 g HDPE tubes and closed with a lid

The tubs and tubes are packed in a carton box

6.6. Special precaution for disposal and other handling

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION:

B.Braun Medical (Pty) Ltd

253 Aintree Road

Northriding

Randburg

2194

8. REGISTRATION NUMBER(S)

W/13.1/275

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

March 1999

10. DATE OF REVISION OF THE TEXT PUBLICATION:

18 August 2022