Patient Information Leaflet for Human Medicine

SCHEDULING STATUS: S0

BIOCREAM ANTISEPTIC CREAM 5 %

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

Read all of this leaflet carefully because it contains important information for you

Biocream antiseptic cream 5 % is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Biocream antiseptic cream 5 % carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Biocream antiseptic cream 5 % with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What Biocream antiseptic cream 5 % is and what it is used for
2. What you need to know before you use Biocream antiseptic cream 5 %
3. How to use Biocream antiseptic cream 5 %

4. Possible side effects
5. How to store Biocream antiseptic cream 5 %
6. Contents of the pack and other information

1. What Biocream antiseptic cream 5 % is and what it is used for

13.1 Antiseptics, Disinfectants and Cleansing agents

Biocream antiseptic cream 5 % is used as an antiseptic for

- Skin infections,
- Burns,
- Cuts, abrasions, wounds, postoperative wounds,
- Decubitus ulcers.

2. What you need to know before you use Biocream antiseptic cream 5 %

Do not use Biocream antiseptic cream 5 %

- if you are hypersensitive (allergic) to Povidone-Iodine, other iodine containing products or any of the other ingredients of Biocream antiseptic cream 5 %.

Warnings and precautions

Special care should be taken with Biocream antiseptic cream 5 %

- If you are allergic to iodine.
- If you are pregnant or lactating women

The product is for external use only

Other medicines and Biocream antiseptic cream 5 %

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- 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.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

The safety of Biocream antiseptic cream 5 % in fertility, pregnancy and breastfeeding has not been established.

Biocream antiseptic cream 5 % should not be used in pregnant or breastfeeding in women.

Driving and using machines

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

3. How to use Biocream antiseptic cream 5 %

Always use Biocream antiseptic cream 5 % exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist, or nurse if you are not sure.

- Biocream antiseptic cream 5 % is for external use only.
- Before applying the Povidone-iodine preparations ensure the area is clean and dry. Povidone-iodine preparations may react with blood or pus and lead to ineffectiveness of the preparation.
- Liberally apply Biocream antiseptic cream 5 % and cover with bandage or dressing
- Change the dressing daily and reapply Biocream antiseptic cream 5 %.

If you use more Biocream antiseptic cream 5 % than you should.

Metabolic acidosis (excess acid in the body fluids) and renal impairment (kidney problems) may occur if applied to large areas or denuded skin.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

4. Possible side effects

Biocream antiseptic cream 5 % can have side effects.

Not all side effects reported Biocream antiseptic cream 5 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Biocream antiseptic cream 5 %, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

Less frequently side effects:

- Hypersensitivity and anaphylactic reaction (allergic reaction)
- skin irritation,
- redness
- swelling
- Hypothyroidism (decreased production of thyroid hormones)
- Metabolic acidosis (excess acid in the body fluids)
- Hypernatraemia (increased sodium levels in the blood)
- Skin reaction localised

Frequency not known side effects

- Renal impairment (kidney problems)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.By reporting side effects, you can help provide more information on the safety of Biocream antiseptic cream 5 %.

5. How to store Biocream antiseptic cream 5 %

Store all medicines out of reach of children.

Store at or below 25 °C.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Biocream antiseptic cream 5 % contains

The active substance is Povidone-Iodine

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

The other ingredients are: Emulgade A6, Eumulgin B25, Cetyl Steryl Alcohol, Liquid Paraffin, Glycerine and Purified water

What Biocream antiseptic cream 5 % looks like and contents of the pack.

Biocream antiseptic cream 5 % is a brown cream with the characteristics and smell of iodine packed in 500 g jars: 25 g tubes.

Holder of Certificate of Registration

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This leaflet was last revised in

18 August 2022

Registration number

W/13.1/275

Access to the corresponding Professional Information

It is contained in the packaging of the medicine