Approved Patient Information Leaflet for Medicines for Human Use:

BETADINE® FIRST AID CREAM

SCHEDULING STATUS S0

BETADINE® FIRST AID CREAM 5 % *w/w* (Topical cream)

Povidone-iodine

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

- BETADINE® FIRST AID CREAM is available without a doctor's prescription for you to treat a mild illness. Nevertheless, you still need to use BETADINE® FIRST AID CREAM carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share BETADINE® FIRST AID CREAM with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What BETADINE® FIRST AID CREAM is and what it is used for
2. What you need to know before you use BETADINE® FIRST AID CREAM
3. How to use BETADINE® FIRST AID CREAM
4. Possible side effects
5. How to store BETADINE® FIRST AID CREAM
6. Contents of the pack and other information

1. What BETADINE® FIRST AID CREAM is and what it is used for

BETADINE® FIRST AID CREAM contains povidone-iodine, which kills a wide range of germs, including bacteria, fungi, viruses and simple organisms.

BETADINE® FIRST AID CREAM is used for the treatment and prevention of infections in minor wounds, cuts, abrasions and burns.

2. What you need to know before you use BETADINE® FIRST AID CREAM

Do not use BETADINE® FIRST AID CREAM

- if you are hypersensitive (allergic) to povidone-iodine or any of the other ingredients of BETADINE® FIRST AID CREAM (listed in section 6).
- if you have an enlarged thyroid gland or any conditions affecting your thyroid.
- Before, during and after radioiodine therapy for hyperthyroidism (an overactive thyroid gland) until a lasting cure has been obtained.
- 4 weeks before radioiodine scintigraphy or radioiodine treatment of thyroid cancer.
- If you are taking products containing mercury, as this can cause skin damage.
- if you are taking a medicine called lithium.
- in children under 2 years of age or children of very low weight (1 500 grams).

Warnings and precautions

Take special care with BETADINE® FIRST AID CREAM

- if you are pregnant of breastfeeding (see below).
- if you currently have any thyroid problems as you may develop an overactive thyroid gland (hyperthyroidism) if you use BETADINE® FIRST AID CREAM. If you have thyroid problems, you should not be exposed to BETADINE® FIRST AID CREAM for long periods of time and over large areas of your skin (e.g. not more than 10 % of your body area should be covered and for not longer than 7 days). Even after treatment, you should look out for early symptoms of hyperthyroidism (feeling tired, increased sensitivity to cold, constipation, weight gain, muscle weakness or pain, enlarged thyroid gland (goitre), which presents as an enlargement of your neck area around the throat).

- special caution is needed if you have kidney problems and regularly apply BETADINE® FIRST AID CREAM to broken skin.
- if you have an allergic or irritant reaction such as redness, small blisters, itching or a rash. If this happens, you should stop using BETADINE® FIRST AID CREAM and you should talk to your doctor or pharmacist.
- BETADINE® FIRST AID CREAM can cause temporary skin discolouration caused by the colour of the product.

For external use only.

Children and adolescents

Do not use in children under 2 years of age or children of very low weight (1 500 grams), as they have an increased risk of developing hypothyroidism (underactive thyroid gland) from the administration of large amounts of iodine. Any possible oral ingestion of BETADINE® FIRST AID CREAM by the infant must be absolutely avoided.

Other medicines and BETADINE® FIRST AID CREAM

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

In particular, you should tell your doctor or pharmacist if you are using the following:

- wound-treatment medicines containing enzymes, silver, hydrogen peroxide and taurolidine.
- antiseptics containing octenidine.

Tell your doctor if you are due to have a thyroid test, faeces (stool) or urine test, as BETADINE® FIRST AID CREAM may affect the results, for up to 4 weeks following treatment.

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 using this

medicine.

During pregnancy and lactation, BETADINE® FIRST AID CREAM 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 new-born to iodine, no large amounts of BETADINE® FIRST AID CREAM should be used during pregnancy and lactation.

Do not apply BETADINE® FIRST AID CREAM to your breast, if you are breastfeeding.

No information is available about the effects of using BETADINE® FIRST AID CREAM on fertility.

Driving and using machines

BETADINE® FIRST AID CREAM has no known effect on the ability to drive and use machines.

3. How to use BETADINE® FIRST AID CREAM

Do not share medicines prescribed for you with any other person.

Always use BETADINE® FIRST AID CREAM exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

BETADINE® FIRST AID CREAM is only to be applied to the skin.

The skin should be cleaned and dried before application.

If required, the affected area can be covered with a dressing or bandage.

If there is no improvement after 7 days of regular use, consult your doctor.

Apply the following amount of BETADINE® FIRST AID CREAM to the affected area (once or twice daily for up to 7 days):

- Children from 2 – 6 years: Apply 1 – 2 small pea sized amounts each day.
- Children from 6 – 8 years: Apply 2 small pea sized amounts twice a day.
- Children from 9 – 13 years: Apply 3 small pea sized amounts twice a day.
- Children from 13 – 18 years: Apply 5 small pea sized amounts twice a day.
- Adults: Apply 8 – 9 small pea sized amounts twice a day.

If you use more BETADINE® FIRST AID CREAM than you should

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

Systemic absorption of iodine from BETADINE® FIRST AID CREAM after repeated application to large areas of wounds or burns or deliberate or accidental ingestion of large quantities of BETADINE® FIRST AID CREAM may lead to a number of overdose effects: metallic taste in mouth, increased saliva production, burning or pain in the throat or mouth, irritation and swelling of the eyes, pulmonary oedema (fluid in the lungs, making it difficult to breathe), skin reactions, upset stomach and diarrhoea, fast heart rate, low blood pressure, fever, metabolic acidosis (high levels of acid in the body), high levels of sodium in the blood (seen with a test) and kidney problems.

If you experience any of the effects listed above, following the use of BETADINE® FIRST AID CREAM, or following deliberate or accidental ingestion, you should contact your doctor, pharmacist or local hospital immediately. Take this leaflet and any other packaging with you so they know what you have been using.

If you forget to use BETADINE® FIRST AID CREAM

Do not apply a double dose to make up for a forgotten dose, simply apply the next dose as planned. Then follow the original instructions for use.

4. Possible side effects

BETADINE® FIRST AID CREAM can have side effects.

Not all side effects reported for BETADINE® FIRST AID CREAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using BETADINE® FIRST AID CREAM, please consult your health care provider for advice.

If any of the following happens, stop using BETADINE® FIRST AID CREAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic type reactions that occur quickly and include an itchy raised skin rash (hives), a body rash, sudden breathing problems, feeling faint, swelling of the mouth, face, lips, tongue and throat.
- Symptoms of an over-active thyroid - symptoms may include feeling nervous, moody, difficultly sleeping, hand tremors, fast or irregular heartbeat, trouble breathing, feeling very hot or sweaty, and weight loss.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BETADINE® FIRST AID CREAM. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects

- Skin redness and / or skin swelling, itching, small blisters.

The frequency of the following side effects is unknown

- Hypothyroidism (insufficient function of thyroid gland, which can cause fatigue, weight gain, slow heart rate) - can occur due to prolonged or extensive use of BETADINE® FIRST AID CREAM.
- The amount of electrolytes in your body is too high or too low (seen in a test) – can occur when large amounts of BETADINE® FIRST AID CREAM are used.
- Increased amounts of acid in your blood (the main symptoms are shortness of breath, confusion and lethargy) – can occur when large amounts of BETADINE® FIRST AID CREAM are used.
- Kidney failure (symptoms include difficulty urinating, thirst and a dry mouth, and pain on one side of your back) – can occur when large amounts of BETADINE® FIRST AID CREAM are used.
- Changes in the chemical properties of the blood serum may occur (seen in a test) after absorption of large amounts of BETADINE® FIRST AID CREAM.
- Skin discolouration.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of BETADINE® FIRST AID CREAM.

Alternately contact iNova Pharmaceuticals at +27 11 087 0000.

Website: www.inovapharma.co.za

5. How to store BETADINE® FIRST AID CREAM

Store at or below 30 °C.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (i.e. toilets).

6. Contents of the pack and other information

What BETADINE® FIRST AID CREAM contains

Each 1 g of cream contains povidone-iodine 50 mg (5 % *w/w*), equivalent to 5 mg available iodine.

The other ingredients are cetostearyl alcohol, glycerol, liquid paraffin, macrogol stearate, polysorbate 60, potassium iodate, purified water, sodium hydroxide, sorbitan stearate, white soft paraffin.

What BETADINE® FIRST AID CREAM looks like and contents of the pack

BETADINE® FIRST AID CREAM is a homogeneous reddish-brown viscous cream, free from lumps.

BETADINE® FIRST AID CREAM is supplied in internal lacquered aluminium tubes containing 15 g or 40 g of product. The tubes are closed with polypropylene or heterophasic copolymer screw caps.

The tubes are enclosed in printed cartons.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Full Professional Information can be found at https://inovapharma.co.za/brands-and-products/professional-information/ or can be obtained upon request from iNova Pharmaceuticals.

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