

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S0

BETADINE® SURGICAL SCRUB 7,5 %

Povidone-iodine

NOT FOR ORAL USE

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

BETADINE® SURGICAL SCRUB is available without a doctor's prescription. Nevertheless, you still need to use BETADINE® SURGICAL SCRUB carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BETADINE® SURGICAL SCRUB 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 14 days.

What is in this leaflet

1. What BETADINE® SURGICAL SCRUB is and what it is used for
2. What you need to know before you use BETADINE® SURGICAL SCRUB
3. How to use BETADINE® SURGICAL SCRUB
4. Possible side effects
5. How to store BETADINE® SURGICAL SCRUB
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1. What BETADINE® SURGICAL SCRUB is and what it is used for

BETADINE® SURGICAL SCRUB contains povidone-iodine, which kills a wide range of germs,

including bacteria, fungi, viruses and simple organisms.

BETADINE® SURGICAL SCRUB is used as an antiseptic for the pre-procedural and post-procedural treatment of the skin.

2. What you need to know before you use BETADINE® SURGICAL SCRUB

Do not use BETADINE® SURGICAL SCRUB

- if you are allergic to povidone-iodine, iodine or any of the other excipients of this medicine (listed in section 6),
- if you have thyroid disorders or goitre,
- during radioiodine scintigraphy or radioiodine treatment of thyroid diseases,
- if you are using medicines which contain mercury,
- in children under 2 years of age,
- in patients on lithium therapy.

Warnings and precautions

- You should not use BETADINE® SURGICAL SCRUB on children younger than 2 years and BETADINE® SURGICAL SCRUB must be applied by an adult.
- If you experience skin irritation or allergy, stop using BETADINE® SURGICAL SCRUB.
- You should not heat BETADINE® SURGICAL SCRUB before use.
- You may experience a temporary change in colour of the skin in the area it was applied.
- Povidone-iodine may permanently discolour white gold jewellery and it is recommended that this type of jewellery be removed before using **BETADINE SURGICAL® SCRUB**.

Children and adolescents

Do not use in children under 2 years of age.

BETADINE® SURGICAL SCRUB must be applied by an adult.

Other medicines and BETADINE® SURGICAL SCRUB

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 taking the following:

- Wound-treatment medicines containing enzymes, mercury, silver, hydrogen peroxide and taurolidine.
- Povidone-iodine products when used before or after application of octenidine may lead to temporary dark discolourations at the application site.

Using this treatment may interfere with tests of thyroid function.

Several types of tests for detecting occur (not visible) blood in faeces or blood in urine may be affected (i.e. produce false-positive results).

Tell your doctor if you are due to have a thyroid test, faeces (stool) or urine test, as BETADINE® SURGICAL SCRUB may affect the 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 using this medicine.

Driving and using machines

BETADINE® SURGICAL SCRUB has no known effect on the ability to drive and use machines.

3. How to use BETADINE® SURGICAL SCRUB

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

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For external use on the skin only.

Adults and children aged 2 years and above:

For external use on the skin only.

Apply up to 5 ml for surgical hand washing and for pre-operative scrubbing.

Rinse off under running water.

If you use more BETADINE® SURGICAL SCRUB 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.

If you forget to use BETADINE® SURGICAL SCRUB

Do not use a double dose to make up for a forgotten dose.

4. Possible side effects

BETADINE® SURGICAL SCRUB can have side effects.

Not all side effects reported for BETADINE® SURGICAL SCRUB are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using BETADINE® SURGICAL SCRUB, please consult your health care provider for advice.

If any of the following happens, stop using BETADINE® SURGICAL SCRUB 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, difficulty 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® SURGICAL SCRUB. 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® SURGICAL SCRUB.
- The amount of electrolytes in your body is too high or too low (seen in a test) – can occur when large amounts of BETADINE® SURGICAL SCRUB 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® SURGICAL SCRUB are used.
- Kidney failure (symptoms include difficulty in urinating, thirst and a dry mouth, and pain in one side of your back) – can occur when large amounts of BETADINE® SURGICAL SCRUB are used.
- Changes in the chemical properties of the blood serum may occur (seen in a test) after absorption of large amounts of BETADINE® SURGICAL SCRUB.
- Chemical skin burns.

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® SURGICAL SCRUB. Alternatively report to: ZADrugSafety@mundipharma.co.za.

5. How to store BETADINE® SURGICAL SCRUB

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original container.
- Do not use after the expiry date shown on the pack after the EXP. The expiry date refers to the last day of that month.
- 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® SURGICAL SCRUB contains

- The active substance is Povidone-iodine 7,5% w/v.
- The other ingredients are Citric Acid Monohydrate, Coco Glucoside, Disodium Phosphate, Glycerol, Hydroxyethyl Cellulose, Potassium Iodate, Sodium Hydroxide, Sodium Laureth Sulfate, Purified Water

What BETADINE® SURGICAL SCRUB looks like and contents of the pack

BETADINE® SURGICAL SCRUB is a reddish-brown, viscous solution supplied in brown HDPE containers with LDPE inserts, fitted with HDPE caps.

The product comes in the following pack sizes: 120ml, 500ml and 1000ml.

Not all pack sizes may be marketed.

BETADINE SURGICAL SCRUB

Povidone- iodine (7,5 % w/v)

Holder of Certificate of Registration

Mundipharma (Pty) Ltd

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South Africa

This leaflet was last revised in

8 April 2025

Registration number

57/13.1/0272

Access to the corresponding Professional Information

Not applicable

® = **Betadine** is a registered trademark