

1. NAME OF THE MEDICINAL PRODUCT

Pyodine Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100g contains:

Povidone-iodine5.0g
(Equivalent to 0.5g available Iodine)

For excipients, see 4.1

3. PHARMACEUTICAL FORM

Gel

PHARMACOLOGICAL CLASSIFICATION:

A 13.1 Antiseptics, disinfectants, cleansing agents.

PHARMACOLOGICAL ACTION:

Povidone-iodine is a multivalent broad spectrum local antiseptic having bactericidal and fungicidal properties. The effect on vegetative cells of various bacteria and fungi is due to the liberation of free iodine from the complex. In vitro studies have also shown some antiviral activity

INDICATIONS:

Pyodine Gel is indicated for the treatment and prevention of the following bacterial, mycotic and viral skin infections:

- Contaminated cuts, abrasions and laceration.
- Post-operative dressing
- Second and third degree burns.
- Skin infections which are secondarily infected.
- All types of topical ulcers (including tuberculous and leprotic)
- Bedsores and after minor surgical procedures

CONTRA-INDICATIONS:

Hypersensitivity to any ingredient of the product.

Dosage and application

Cover the affected area of skin with Pyodine Gel and apply occlusive dressing. Twice daily application is sufficient. In burn and other chronic wounds thrice daily applications are required

WARNINGS:

1. Not to be used by persons who are allergic to iodine.
2. Not to be used in pregnancy or by lactating women.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Hypersensitivity and local irritation may occur. However, if irritation, swelling or redness occur, discontinue treatment and consult your physician.
Hypothyroidism may occur after topical application to neonates. Absorption of povidone-iodine may interfere with thyroid function tests.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF TREATMENT:

Systemic effects include metabolic acidosis, hypernatraemia and renal impairment. These effects could occur if applied to large areas or denuded skin. Treatment is symptomatic and supportive.

4. PHARMACEUTICAL PARTICULARS**4.1. LIST OF EXCIPIENTS:**

- Polyethylene Glycol 400 Liquid
- Polyethylene Glycol 4000 (Flakes)
- Sodium Hydroxide
- Purified water

4.2 INCOMPATIBILITIES:

None Known

4.3 SHELF LIFE:

03 years

4.4 SPECIAL PRECAUTIONS FOR STORAGE:

Store at temperature below 30°C away from light.

4.5 NATURE AND CONTENTS OF CONTAINER:

Bleach board pack containing aluminium tube with plastic cap and insert.
Pack of 20g tube in a carton.

4.6 MARKETING AUTHORIZATION NUMBER

018358

4.6 MARKETING AUTHORISATION HOLDER

Brookes Pharma Private Limited
58 & 59, Sector 15, Korangi Industrial Area, Karachi-Pakistan