SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ROUGEDINE ® 7.5%, cutaneous solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Povidone-iodine..... 7.5 g
Per 100 ml.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for cutaneous application.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- Cleansing and adjunctive treatment in skin and mucous membrane conditions that are primarily bacterial or susceptible to superinfection.

- Antiseptic hand washing of healthcare staff and surgeon's hands

- Preoperative antiseptic washing.

Note: Antiseptic agents are not sterilizing. They temporarily reduce the number of microorganisms.

4.2. Posology and method of administration

Cutaneous route.
For hygienic hand washing, use the product undiluted by pouring 4 ml onto pre-moistened hands. Rub for 1 minute and rinse thoroughly with water.
For surgical hand washing, repeat this protocol for 3 to 5 minutes, on the hands and forearms.
For cleansing soiled wounds, use the product diluted one-third. Rinse thoroughly with water.
Preparation of the surgical patient:
The preparation of the patient for surgery must be carried out less than two hours before the procedure.
A shower is taken on the morning of the procedure using the undiluted product:

- Thoroughly wet your head, hair and entire body in the shower.

- Perform the antiseptic handwashing in four steps:

- Rub 10 ml of ROUGÉDINE 7.5% into the head and hair until the lather lightens. Do not rinse.

- Rub 10 ml of ROUGÉDINE 7.5% onto the torso and upper limbs until the foam is no longer discolored, paying particular attention to the armpits and navel.
  Do not rinse.

- Rub 10 ml of ROUGÉDINE 7.5% onto the genital area and lower limbs until the foam is no longer discolored, paying particular attention to the genitals, the intergluteal cleft, and between the toes. Do not rinse.

- Rinse the entire body thoroughly.

- Repeat the washing process following the same procedure. Rinse, then dry with a clean towel and put on clean clothes.

4.3. Contraindications

This medication MUST NOT BE USED in the following situations:

- A history of hypersensitivity to any of the ingredients, particularly povidone, is a contraindication. There are no known cross-reactions with iodinated contrast agents. Intolerance reactions (anaphylactoid reactions) to iodinated contrast agents or anaphylaxis to seafood are not contraindications to the use of ROUGÉDINE 7.5%.

- For the disinfection of medical and surgical equipment.

- Child under 1 year old.

- Prolonged use during the 2nd and 3rd trimesters of pregnancy.

- Breastfeeding is contraindicated in case of prolonged treatment.

- Hyperthyroidism and other acute thyroid diseases .

- Before, during and after administration of radioactive iodine (see section 4.5) .

- Use with products containing mercury (see section 4.5) .

4.4. Special warnings and precautions for use

Special warnings

Due to transcutaneous absorption of iodine, repeated or prolonged treatment may expose to a risk of systemic effects, particularly thyroid dysfunction (see section 4.8).
These systemic effects, favored by repeated applications, are all the more to be feared when the antiseptic is used on a large area, under occlusive dressing, on damaged skin (especially burned), mucous membranes, the skin of premature infants or newborns (due to the surface area/weight ratio and the occlusive effect of diapers in the diaper area).
Special care is required when applying regularly to damaged skin in patients with renal insufficiency, particularly in patients with extensive burns (see section 4.8).
Contraindicated in children under 12 months, use in children under 30 months, if it proves essential, will be limited to a brief and small application and will be followed by washing with sterile water.
This medicine contains 52.5 mg of benzoic acid per 100 ml. Benzoic acid may cause local irritation.
Microbial contamination is possible as soon as the packaging of an antiseptic preparation is opened.
Bottles with a volume greater than 250 ml pose a risk of contamination of the solution if used for an extended period after opening.

Precautions for use

Rinse after use.
Use with caution in all conditions which may promote systemic absorption and particularly in children under 30 months (see section 4.3).
When preparing the patient for surgery, avoid dripping and maceration between the patient and the operating table sheet. Prolonged contact with the undried solution may cause irritation and, rarely, severe skin reactions such as burns. If skin irritation, contact dermatitis, or hypersensitivity occurs, discontinue use. Do not heat before application.

4.5. Interactions with other medicinal products and other forms of interaction

Given the possible interferences (antagonism, inactivation), the simultaneous or successive use of antiseptics should be avoided.
Products containing mercury can react with povidone iodine to form mercury iodide, which is highly corrosive .
Povidone-iodine can reduce iodine uptake by the thyroid gland. Therefore, its use can interfere with thyroid examinations (scintigraphy, protein-bound iodine testing, diagnostic tests with radioactive iodine) and make radioactive iodine treatment impossible . It is advisable to wait four weeks after applying povidone-iodine before undergoing any examination or radioactive iodine treatment .

4.6. Fertility, pregnancy and breastfeeding

Pregnancy

Animal studies have not shown any teratogenic effects. In the absence of teratogenic effects in animals, malformations in humans are not expected. Indeed, to date, substances responsible for malformations in humans have been shown to be teratogenic in animals in well-conducted studies on two species.
In clinical practice, there is currently insufficient data to assess a possible malformative effect of povidone iodine when administered during the first trimester of pregnancy.
The fetal thyroid begins to take up iodine after 14 weeks of amenorrhea; no impact on the fetal thyroid is expected in the case of prior administrations.
Iodine overload, very likely with prolonged use of this product beyond this period, can lead to fetal hypothyroidism, biological or even clinical (goiter).
This is reversible if administered during the 2nd trimester, but at the end of pregnancy, it can lead to a goiter.
Therefore, as a precaution, it is best not to use this medication during the first trimester of pregnancy.
In case of prolonged use, its use is contraindicated from the 2nd trimester onwards.
Its use on an occasional basis should only be considered if necessary.

Breastfeeding

Iodine passes into breast milk at concentrations higher than in maternal plasma. Due to the risk of hypothyroidism in the infant, breastfeeding is contraindicated during prolonged treatment with this medication.

Fertility

Current data on the fertility of povidone-iodine are limited.

4.7. Effects on the ability to drive vehicles and use machinery

Not applicable.

4.8. Undersirable effects

The frequency of adverse reactions have been classified as follows: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1,000), very rare (<1/10,000), not known (cannot be estimated from the available data).
Immune system disorders
Undetermined Hypersensitivity
Undetermined Anaphylactic reaction: urticaria, Quincke's edema, anaphylactic shock, anaphylactoid reaction.
Endocrine disorders
Undetermined. With repeated and prolonged administration, iodine overload may occur, potentially leading to thyroid dysfunction, particularly in premature infants, newborns, and patients with extensive burns. Rare cases of hyperthyroidism have been reported.*
Undetermined Hypothyroidism **
Metabolism and nutrition disorders
Undetermined Metabolic acidosis ***
Undetermined Electrolyte imbalance
Skin and subcutaneous tissue disorders
Undetermined Contact dermatitis (with symptoms such as erythema, blisters and pruritus) with a burn-like appearance in case of maceration.
Undetermined Angioedema
Undetermined. Cases of reversible and transient brown skin discoloration have been reported (this discoloration washes off with water).
Kidney and urinary tract disorders
Undetermined Acute renal failure ***
Undetermined Abnormal blood osmolarity ***
Injuries, poisonings and complications related to procedures
Undetermined Chemical burn, 1st to 3rd degree ****

** In patients with a history of thyroid disease (see section 4.4), after significant absorption of iodine, for example, in the case of repeated use for the treatment of wounds or burns over large areas.*

*** Hypothyroidism after prolonged or extensive use of povidone iodine.*

**** May occur through absorption of large volumes of povidone iodine following exposure of large skin or mucous membrane areas (e.g., treatment of burns).*

***** May occur in case of maceration under the patient in the pre-operative period*

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals report any suspected adverse reactions using the FRILAB reporting form available under the pharmacovigilance tab of the website: www.frilab.ch .

4.9. Overdose

An overdose is not expected under normal conditions of use.
Accidental ingestion of large volumes of povidone-iodine, or absorption of large volumes through exposure of large areas of skin or mucous membranes (healthy or damaged), can lead to severe systemic iodine poisoning. Systemic iodine poisoning may cause abdominal pain, bloody vomiting and diarrhea, tachycardia, hypotension, circulatory failure, glottic edema leading to asphyxia or pulmonary edema, aspiration pneumonia, seizures, fever, metabolic acidosis, hypernatremia, and/or renal failure (including anuria). Hyperthyroidism or hypothyroidism may also develop.
The treatment , to be carried out in a specialized setting, is symptomatic and adapted according to needs.
Given the foaming nature of this solution, do not perform gastric lavage.
In cases of severe hypotension, an intravenous solution should be administered; vasopressors should be added if necessary.
Endotracheal intubation may be necessary if caustic injury to the upper airway results in significant swelling and edema.
Vomiting should not be induced. The patient should be kept in a position that maintains a clear airway and prevents aspiration (in case of vomiting).
If the patient is not vomiting and can tolerate oral feeding, ingesting starchy foods (e.g., potato, flour, cornstarch, bread) can help convert iodine to the less toxic iodide. In the absence of signs of intestinal perforation, gastric irrigation with a starch solution via a nasogastric tube can be used (the gastric effluent turns dark blue-violet, and this color can be used as a guide to determine when the irrigation is complete).
Hemodialysis effectively removes iodine and should be used in severe cases of iodine poisoning, particularly in cases of renal failure. Continuous venovenous hemofiltration is less effective than hemodialysis.
In case of thyroid dysfunction, treatment with povidone iodine should be discontinued.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class: Antiseptics and disinfectants, ATC code: D08AG02.
Broad-spectrum antiseptic with bactericidal, yeasticidal and virucidal properties.
Antiseptic group: iodine derivatives.
Its spectrum of activity is that of iodine, released slowly and progressively:

- bactericidal in less than 5 minutes, in vitro, on all bacteria;

- yeasticide.

Organic matter (proteins, serum, blood…) reduces the activity of free iodine, the active form of this product.

Iodophores are unstable at alkaline pH.
Skin coated with povidone iodine takes on a brown color which is easily removed with water.

5.2. Pharmacokinetic properties

The available iodine from povidone-iodine can cross the skin barrier.
Its elimination will occur primarily through the urinary tract.
Povidone alone cannot, under any circumstances, lead to systemic absorption.

5.3. Preclinical safety data

Acute toxicity

In acute toxicity studies in mice, rats, rabbits and dogs, after systemic administration (oral, ip, iv) toxic effects were observed only with excessively high doses which are not significant for local use of a povidone iodine solution.
Thus the LD50 in rodents is greater than 200 mg/kg of available iodine (equivalent to 20 ml per kg of a pure 10% PVP-I solution) and by intraperitoneal route, greater than 30 mg of available iodine per kg (equivalent to 3 ml per kg of an undiluted 10% PVP-I solution).

Chronic toxicity

Subchronic and chronic toxicity studies were conducted in rats, administering povidone-iodine (10% available iodine) in the diet at doses ranging from 75 to 750 mg of povidone-iodine per kg of body weight per day for up to 12 weeks. After discontinuation of povidone-iodine administration, dose-dependent and reversible increases in serum protein-bound iodine and nonspecific histopathological changes in the thyroid gland were observed. Similar changes also occurred in the control group, which received potassium iodide in an iodine-equivalent amount instead of povidone-iodine.
In chronic IP treatment in rats from a dose of 5 mg/kg of PVP-I, severe peritonitis with adhesion of intra-abdominal organs is observed, which can lead to the death of the animal.

Mutagenic and carcinogenic potential

PVP-I has no mutagenic properties.
No carcinogenicity studies have been conducted.

Reproductive and developmental toxicity

A reproductive toxicity study was conducted in rabbits. Doses of 16, 35 and 75 mg/kg body weight per day were administered intramuscularly to pregnant female rabbits for 12 days from the 6th ^{to} the 18th ^{day} of gestation.
PVP-I was not teratogenic.
No animal fertility studies have been conducted.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Glycerin, nonylphenol 9,5, disodium phosphate dihydrate, citric acid monohydrate, potassium iodide, tridecyl alcohol ethoxylate, sodium N-lauryl sarcasinate, purified water

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

Store at a temperature not exceeding 30°C.

6.5. Nature and contents of container

125 ml in a bottle (HDPE).

6.6. Special precautions for disposal and handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER AND OPERATOR

FRILAB SA
17 RUE DES PIERRES DU NITON
1207 GENEVA - SWITZERLAND

8. MANUFACTURER

NANZ MED SCIENCE PHARMA PVT LTD
Rampur Ghat – Paonta Sahib,
Dist. Sirmour, HP 173025
India

9. DATE OF REVISION OF THE TEXT

April 2024

10. DOSIMETRY

Not applicable.

CONDITIONS FOR PRESCRIPTION AND DISPENSING

This medication is not subject to medical prescription.