SUMMARY PRODUCT CHARACTERISTIC (SPC)

BETAIODINE®
7.5% Liquid soap

1. NAME OF THE MEDICINAL PRODUCT – Betaiodine

2. INTERNATIONAL NON-PROPERTY NAME – Povidone Iodine

3. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each ml of Betaiodine, 7.5% liquid soap, contains: ***active ingredient:*** povidone iodine – 75 mg.
For a full list of excipients see section 6.1.

4. PHARMACEUTICAL FORM
Liquid soap
A brown colored liquid having a characteristic iodine odor.

5. CLINICAL PARTICULARS
5.1 Therapeutic indications
BETAIODINE 7.5% Liquid soap is a broad-spectrum antiseptic for topical use. It is indicated for pre-operative hand disinfection by the surgical team, or for disinfecting the site of incision prior to elective surgery.

5.2 Posology and method of administration
Pre-operative surgical scrub - after first wetting the hands and arms with water, approximately 3.5ml of BETAIODINE 7.5% Liquid soap is applied and rubbed thoroughly on to these areas. A brush may be used to scrub the nails. A little water is added to develop a lather and finally this **must be rinsed off** with running water.
Pre-operative skin preparation - the site of incision should be washed with BETAIODINE 7.5% Liquid soap two or three times a day prior to the operation. Immediately before surgery the skin should be moistened with water, BETAIODINE 7.5% Liquid soap applied and rubbed thoroughly into the area for several minutes. A sterile gauze swab is used to develop a lather which **must be finally rinsed off** with water.
Only water should be used to dilute BETAIODINE 7.5% Liquid soap.
Neonates:
Do not use on neonates, refer to Section 4.3 Contraindications.
Children and Elderly:
There are no special dosage recommendations for children or elderly patients.
Renal Impairment:
Patients with renal impairment should refer to Section 4.4, special warnings
and precautions for use.

5.3 Contraindications
BETAIODINE 7.5% Liquid soap must never be administered orally, and is contra-indicated in neonates, and during pregnancy and lactation.
Regular or prolonged use should be avoided in patients with thyroid disorders or those receiving lithium therapy.
Hypersensitivity to any of the ingredients.

5.4 Special warnings and precautions for use

Care must be taken when BETAIODINE 7.5% Liquid soap is used on known iodine-sensitive subjects, although such people do not normally react to iodinated povidone.

The application of povidone-iodine to large wounds or severe burns may produce systemic adverse effects such as metabolic acidosis, hypernatraemia, and impairment of renal function.

5.5 Interactions with other medicinal products and other forms of interaction

It is to be expected that povidone-iodine reacts with protein and various other organic substances such as blood and pus components, for example. This interaction may impair efficacy.

As a result of oxidation, the concomitant application of BETAIODINE 7.5% Liquid soap and enzymatic wound treatment agents weakens the action of the enzyme components of both drugs. The latter is also true of hydrogen peroxide and taurolidine as well as of disinfectants containing silver (formation of silver iodide).

BETAIODINE 7.5% Liquid soap must not be used concomitantly or immediately following disinfectants containing mercury (risk of chemical burns due to the formation of mercury iodide).

BETAIODINE 7.5% Liquid soap must not be used concomitantly with or immediately after the application of octenidine-based antiseptics to the same or adjacent areas as transient dark discolouration can occur at the areas concerned.

In patients receiving concomitant lithium therapy, regular application of In patients receiving concomitant lithium therapy, regular application of

BETAIODINE 7.5% Liquid soap should be avoided as, especially in the case of application of povidone-iodine to extensive areas, larger amounts of iodine may be absorbed. In exceptional cases, this can induce (transient) hypothyroidism. In this special situation, a synergistic effect might also occur as lithium may also induce hypothyroidism. should be avoided as, especially in the case of application of povidone-iodine to extensive areas, larger amounts of iodine may be absorbed. In exceptional cases, this can induce (transient) hypothyroidism. In this special situation, a synergistic effect might also occur as lithium may also induce hypothyroidism.

Effect on diagnostic tests

Due to the oxidising action of povidone-iodine, when patients are undergoing treatment with BETAIODINE 7.5% Liquid soap various diagnostic agents can give false-positive results (inter alia toluidine and guaiac resin for the determination of haemoglobin or glucose in the stools or urine).

During the application of povidone-iodine uptake of iodine by the thyroid gland may be reduced; this can lead to disturbances in thyroid scanning, PBI (protein-bound iodine) determination and radioiodine diagnostics and make planned radioiodine therapy impossible. A waiting period of at least 1-2 weeks should be observed after discontinuing the povidone-iodine treatment before conducting a new thyroid scan.

5.6 Pregnancy and lactation

BETAIODINE 7.5% Liquid soap is not recommended for use during pregnancy because of the possibility of absorption through skin and subsequent interference with tests of neonatal thyroid function. BETAIODINE 7.5% Liquid soap should not be used in neonates or during lactation. Refer to Section 4.3, Contraindications.

5.7 Effects on ability to drive and use machines

None stated.

5.8 Undesirable effects

In very rare instances BETAIODINE 7.5% Liquid soap may produce skin reactions in iodine-sensitive subjects. These reactions subside on cessation of treatment.

System Organ Class	Very Common (≥1/10)	Common (≥1/100 to < 1/10)	Uncommon (≥1/1,000 to < 1/100)	Rare (≥1/10,000 to < 1/1,000)	Very Rare (< 1/10,000)	Not known (cannot be estimated from the data available)
Skin and Subcutaneous Tissue Disorders					Skin irritation	

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

5.9 Overdose
In cases where BETAIODINE 7.5% Liquid soap has been taken orally, gastric lavage with dilute starch mucilage or a 1% solution of sodium thiosulphate must be administered. The electrolyte balance must be corrected and lost fluids replaced.

6. PHARMACOLOGICAL PROPERTIES

6.1 Pharmacodynamic properties
ATC Code: D08AG02
Dermatologicals/Antiseptics and Disinfectants/povidone-iodine
Povidone-iodine has antiseptic activity and is mainly used for the treatment of contaminated wounds and pre-operative preparation of skin and mucous membranes. It is considered to be less irritant than iodine.

6.2 Pharmacokinetic properties
Povidone-iodine is slightly absorbed when applied to the skin. Iodides are excreted mainly in the urine, with smaller amounts appearing in the faeces, saliva and sweat.

6.3 Preclinical safety data
Povidone-iodine had a low acute toxicity in both dogs and rats following either oral or intraperitoneal administration. Absorption of iodine through intact skin is low following the application of solutions of povidone-iodine although systemic absorption of iodine is greatly increased if the solutions are applied to broken skin, mucous membranes or are introduced into the cavities of the body. At subcutaneous dose levels of up to 75mg/kg/day, povidoneiodine was non-teratogenic in rabbits following administration to pregnant animals during the period of organogenesis.
Some early *in vitro* studies indicated a possible mutagenic action for povidone-iodine. However, a number of later studies, using *in vitro* and *in vivo* test systems, do not indicate a significant level of mutagenic/genotoxic activity for povidone-iodine. Although conflicting data have been published, there is no convincing evidence to suggest that iodinated povidone adversely affects wound healing. Concentrations of 0.05 and 0.5% povidone-iodine did not cause significant ocular damage when administered into the vitreous cavities of rabbits' eyes. There is some evidence to suggest that povidoneiodine-containing solutions applied to the round window of the chinchilla ear could result in high frequency hearing loss.

7 PHARMACEUTICAL PARTICULARS

7.1 List of excipients

Sodium hydroxide,
citric acid,
sodium laureth sulfate,
sodium chloride,
cocamide DEA,
water purified.

7.2. Incompatibilities

Povidone-iodine is incompatible with reducing agents, alkaloid salts, tannic acid, salicylic acid, silver, mercury and bismuth salts, taurolidine and hydrogen peroxide (see also 4.5 "Interactions with other medicaments and other forms of interaction").

7.3 Shelf life

3 years unopened. Use after opening till expiration date. Do not use after the expiration date

7.4. Special precautions for storage

Store in a dry place, out of the reach of children at a temperature not higher than 15^0C. Protect from light.

7.5 Nature and contents of container

80 ml liquid soap is filled into labeled plastic bottle, inserted with leaflet in cardboard box.
1liter liquid soap is filled into labeled plastic container.
3liters liquid soap are filled into labeled plastic container.

7.6 Special precautions for disposal

No special requirements.

8. MANUFACTURER

"ARPIMED" LLC
Bldg. 19, mcr 2-nd, Abovyan, Kotayki Marz, Republic of Armenia
Tel.: (374) 222 21703 Fax: (374) 222 21924

9. MARKETING AUTHORIZATION HOLDER

"ARPIMED" LLC
Bldg. 19, mcr 2-nd, Abovyan, Kotayki Marz, Republic of Armenia
Tel.: (374) 222 21703 Fax: (374) 222 21924

10. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27.12.2002 (DATE OF FIRST AUTHORISATION)

11. DATE OF REVISION OF THE TEXT