**SUMMARY OF PRODUCT CHARACTERISTICS**

**BETAIODINE**

**1% mouthwash solution**

POVIDONE IODINE

**1. NAME OF THE MEDICAL PRODUCT -** BETAIODINE 1% mouthwash solution

**2. Qualitative and quantitative composition**

Each ml of Betaiodine, 1% mouthwash solution contains povidone iodine – 10 mg
For the full list of excipients, see section 6.1.

**3. Pharmaceutical form**

Mouthwash solution.

A dark brown colored liquid having a characteristic menthol odor.

**4 Clinical particulars**

**4.1 Therapeutic indications**

This solution is used for the treatment of Acute Mucosal Infections of the mouth and pharynx e.g. gingivitis, mouth ulcers, for oral hygiene prior to, during, and after dental and oral surgery.

**4.2 Posology and method of administration**

Route of administration: Oral, as a gargle and mouthwash. The product should not be swallowed.
Adults, the elderly and children over 6 years of age: Use diluted with an equal volume of warm water. Gargle or rinse with up to 10 ml for up to 30 seconds without swallowing. Repeat up to four times daily, for up to 14 consecutive days, or as directed.

Not to be used in children of 6 years and under.

**4.3 Contraindications**

Hypersensitivity to iodine or to any excipient. History of abnormal thyroid function or goitre (in particular nodular colloid goitre, endemic goitre and Hashimoto's thyroiditis). Regular use should be avoided in patients on concurrent lithium therapy. Do not use in children of 6 years and under.

**4.4 Special warnings and precautions for use**

Use of this preparation may interfere with tests of thyroid function. Iodine is absorbed through burns and broken skin and to a lesser extent through intact skin and may lead to toxic levels of iodine in the blood, particularly in patients with renal insufficiency. If symptoms occur suggesting changes in thyroid function, these should be investigated. In patients with impaired renal function, blood levels of iodine should be monitored.

Do not use for more than 14 days.

If local irritation and hypersensitivity develop, then discontinue treatment.
Refer to section 4.8 for further information.

Betaiodine gargle and mouthwash can permanently discolour silver jewellery should be removed before using Betaiodine mouthwash solution.

**4.5 Interaction with other medicinal products and other forms of interaction**

Use with concurrent lithium therapy has been shown to exhibit additive hypothyroidic effects.
Absorption of iodine from povidone iodine through either intact skin or broken skin may interfere with thyroid function tests.
Contamination with povidone iodine of several types of tests for the detection of occult blood in faeces or blood in urine may produce false-positive results.

**4.6 Fertility, Pregnancy and lactation**

Iodine freely crosses the placenta and is secreted in breast milk. Thyroid function disorders have been reported in the offspring of mothers exposed to pharmacological doses of iodine. Povidone iodine should not be used regularly during pregnancy unless there is no alternative treatment available.

**4.7 Effects on ability to drive and use machines**

None stated.

**4.8 Undesirable effects**

Local irritation, skin burns and sensitivity reactions have been reported rarely.
Anaphylactic reactions, anaphylactoid reactions and anaphylactic shock have been reported uncommonly with products containing povidone-iodine or povidone.
Excess iodine can produce goitre and hypothyroidism or hyperthyroidism.

Such effects have occasionally been seen with extensive or prolonged use of povidone iodine. Other effects that have been reported are metabolic acidosis and acute renal failure.

### 4.9 Overdose

Deliberate or accidental ingestion of large quantities of povidone iodine will result in high blood concentrations of iodine and gastrointestinal corrosive effects including vomiting, diarrhoea and abdominal pain. Systemic toxicity may result in shock, hypotension, tachycardia, fever, metabolic acidosis and renal impairment. Symptomatic and supportive treatment should be started with special attention to monitoring electrolyte balance, renal function, thyroid function and liver function. Haemodialysis effectively clears iodine and should be employed in severe cases of iodine poisoning particularly if renal failure is present. Continuous venovenous haemodiafiltration is less effective than haemodialysis.

**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. Healthcare professionals are asked to report any suspected adverse reactions via Arpimed “LLC” by going to www.arpimed.com and fill out the appropriate form ″**Report an adverse reaction or inefficiency of dru**g″. Hotline number: (+374 55) 05 79 86. And by using Scientific Centre of Drug and Medical Technology Expertise after academician E. Gabrielyan ″CJSC ″, going to the site: www.pharm.am in ″Report about adverse effect of medicine″ section and fill out the ″Report of adverse reaction or manufacturing problem of medicinal product″.
Hotline numbers: +374 (10) 20 05 05; +374 (96) 22 05 05.

## 5 Pharmacological properties

### 5.1 Pharmacodynamic properties

Antiseptics and disinfectants; ATC code - D08AG02

Betaiodine mouthwash solution contains povidone-iodine, a complex of iodine which shows all the broad spectrum germicidal activity of povidone iodine.
The germicidal activity is maintained in the presence of blood, pus, serum and necrotic tissue.

Betaiodine mouthwash solution kills bacteria, viruses, fungi, spores and protozoa.

### 5.2 Pharmacokinetic properties

The product is intended for topical application to the mouth and buccal cavity.

### 5.3 Preclinical safety data

None stated.

## 6 Pharmaceutical particulars

### 6.1 List of excipients

Saccharin sodium

Ethanol 96%

Menthol

Water purified.

### 6.2 Incompatibilities

None stated.

### 6.3 Shelf life

24 months unopened.

Shelf life 6 months from date of opening.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

### 6.4 Special precautions for storage

• Store out of reach of children, in a dry place, protected from light, at a temperature not exceeding 25°C.

• **Do not swallow!**

### 6.5 Nature and contents of container

100 ml 1% mouthwash solution is filled into glass bottle closed with cap (inside package).

1 labeled glass bottle is inserted together with the leaflet into cardboard box (outer package).

120 ml 1% mouthwash solution is filled into glass bottle closed with cap (inside package).

1 labeled glass bottle is inserted together with the leaflet into cardboard box (outer package).

**6.6 Special precautions for disposal and other handling**

No special requirements.

**7. Marketing Authorisation Holder**

**“Arpimed” LLC**

Kotayk Marz, Abovyan, 2204, 2nd Micro-District, 19 Building, Republic of Armenia

Tel.: (374) 222 21703, Fax: (374) 222 21924

**8. Date of first authorisation**

27.12.2002

**9. Date of revision of the text**