IPODINE

1. **Product Name**

   Ipodine

2. Name and Strength of Active Ingredient

Each ml contains 10% of iodine available in the form of complex of iodine with povidone.

3. Product Description

Deep brown solution with characteristic odor of iodine

4. Pharmacodynamics / Pharmacokinetics

Ipodine is an iodophore which is loose complex of iodine and carrier polymers. Solution of povidone-iodine gradually releases iodine to exert an effect against bacteria, fungi, viruses, protozoa, cysts, and spores. Iodine has a wide spectra of activity including germicide, bactericidal activity against gram-positive and gram-negative bacteria and fungicidal, protozoacidal, cysticidal, virucidal, and some sporicidal activity. It has been suggested that iodine has a lethal effect on microorganisms by reacting with basic NH groups present on amino acids and on the bases of nucleotides forming the corresponding *N*-iododerivatives; by oxidizing the sulfhydryl (SH) group of cysteine, resulting in disruption of protein synthesis; by reacting with the phenolic group of tyrosine, resulting in steric hindrance in hydrogen bonding involving this amino acid; and by reacting with carbon-carbon double bonds of unsaturated fatty acids, resulting in disruption of the physical properties of lipids.

5. Indications

Ipodine is used topically as antiseptics in the management of minor, superficial skin wounds.

6. Recommended Dosage

Clean the affected area. Apply a small amount of this medicine to the area 1-3 times daily. The area may be covered with a sterile bandage. If bandaged, let dry first. Do not use this product longer than 1 week unless directed by a doctor. If forget to use it, use it whenever remember.

7. Route of Administration

Topical use only

8. Contraindications

8.1 Patients who are hypersensitive to povidone iodine or any of the ingredients of this formulation.

8.2 Patients who have or have ever had, a thyroid problem, including swelling (nodular colloid goiter, endemic goiter or Harishimoto's thyroiditis), as using this medicine in these circumstances can further affect the function of your thyroid.

9. Warnings/Precautions

9.1 Patients who are have ever had allergy to this or any other medicines.

9.2 Patients who are have deep puncture wounds, animal bites, serious burns.

9.3 Patients who are have thyroid disorders or are receiving lithium therapy.

9.4 Do not use Ipodine in the eyes or over large areas of the body. To avoid irritation, surfaces to which the medicine is applied should not be covered.

9.5 Do not use Ipodine for longer than 1 week unless directed by a doctor. Prolonged exposure may cause irritation or rarely severe skin reactions.

9.6 Do not heat prior to application.

9.7 Ipodine is for external use only. Keep out of reach of children

10. Interactions with Other Medicaments

Before using Ipodine, Patients must inform their doctor or pharmacist if they are taking or have recently taken, any other medicines including medicines obtained without a prescription, herbal and supplementary medicines. In particular they should tell their doctor if they are taking the following:

Lithium (for depression) can interact with Ipodine to affect the function of the thyroid gland. Therefore, concurrent use should be avoided.

11. Pregnancy and Lactation

Pregnancy:
Povidone-iodine is absorbed systemically as iodine following topical administration to the vaginal mucosa. Following vaginal administration as a douche, iodine concentrations are increased in the maternal urine, amniotic fluid, cord blood and fetal thyroid. Transient hypothyroidism in the newborn has been reported following topical use prior to delivery.

Lactation:
Iodine can be detected in breast-milk following topical application of povidone-iodine.

Excessive use of povidone-iodine should be avoided in pregnant or lactating women. Under these circumstances, povidone-iodine should only be administered if clearly necessary.

12. Adverse Effects

Ipodine can cause hypersensitivity reactions and irritation of the skin and mucous membranes. The application of Ipodine to severe burns or to large areas otherwise denuded of skin may produce the systemic adverse effects associated with iodine and metabolic acidosis, hypernatremia, and renal impairment. Hyperthyroidism or hypothyroidism may occur after ingestion or absorption of large quantities.
Prolonged exposure may cause irritation, or, rarely, severe skin reactions.

13. Overdose and Treatment

Symptoms
The toxic dose depends on the product and the route of exposure. Povidone-iodine (Iodophores) is generally less toxic, as iodine is released slowly. However, significant systemic absorption has occurred in patients receiving povidone-iodine treatment on areas of skin breakdown. Systemic absorption of iodine may occur after chronic applications of less concentrated products.
The manifestations of acute iodine ingestion are related largely to the corrosive effect on mucous membranes and the GI tract.

- Inhalation of iodine vapor can cause severe pulmonary irritation, which can lead to pulmonary edema.
- Skin and eye exposures may result in severe corrosive burns.
- Ingestion can cause corrosive gastroenteritis with vomiting, hematemesis, and diarrhea which can result in significant volume loss and circulatory collapse. Pharyngeal swelling and glottic edema have been reported. Mucous membranes are usually stained brown, and the vomitus may be blue if starchy foods are already present in the stomach.
- Chronic ingestions or absorption may result in hypothyroidism and goiter, or hyperthyroidism. Iodides cross the placenta, and neonatal hypothyroidism and death from respiratory distress secondary to goiter have been reported.

- Chronic iodine deficiency can lead to hypothyroidism and goiter.

Treatment

- Emergency and supportive measures: Maintain an open airway and perform endotracheal intubation if airway edema is progressive. Treat bronchospasm and pulmonary edema if they occur. Treat fluid loss from gastroenteritis aggressively with IV crystalloid solutions. If corrosive injury to the esophagus or stomach is suspected, consult a gastroenterologist to perform endoscopy.
- Antidotes: Sodium thiosulfate may convert iodine to iodide and tetrathionate but is not recommended for intravenous use because iodine is converted rapidly to iodide in the body.
- Once absorbed into the circulation, iodine is converted rapidly to the far less toxic iodide. Therefore, there is no need for enhanced drug removal.
- Decontamination
    - Inhalation. Remove the victim from exposure.
    - Skin and eyes. Remove contaminated clothing and flush exposed skin with water. Irrigate exposed eyes copiously with tepid water or saline for at least 15 minutes.
    - Ingestion. Do not induce vomiting because of the corrosive effects of iodine. Administer a starchy food (potato, flour, or cornstarch) or milk to lessen GI irritation. Activated charcoal does bind iodine in vitro but is of unknown efficacy.

14. Storage Conditions

Keep this medicine below 30 ^{o}C and away from direct heat and light. Keep out of reach and sight of children.

15. Dosage Forms and Packaging Available

Bottle of 30 and 450 ml.

16. Name and Address of Manufacturing

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

75/1 Rama VI Rd., Ratchathewi, Bangkok, Thailand

17. Date of Revision of Package Insert

26 September 2017