

### **1.3 Product Information**

#### **1.3.1 Summary of Product Characteristics (SmPC)**

##### **1. NAME OF THE MEDICINAL PRODUCT**

WOSAN OINTMENT

##### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Povidone Iodine USP.....5% w/w

Water Soluble Ointment Base.....Q.s.

##### **3. PHARMACEUTICAL FORM**

Ointment

A deep brown semi-solid ointment with a smooth texture.

##### **4. CLINICAL PARTICULARS**

###### **4.1 Therapeutic indications**

Wosan<sup>®</sup> Ointment is a broad-spectrum antiseptic for the topical treatment or prevention of infection in minor cuts and abrasions, minor surgical procedures, contaminated wounds, small areas of burns, pre-operative preparation of the skin and mucous membranes, as well as disinfection of equipment. It is also used in the treatment of mycotic and bacterial skin infections pyodermas as well as treatment of infections in decubitus and stasis ulcers.

###### **4.2 Posology and method of administration**

Wosan Ointment is applied topically, directly to the area of the skin affected as directed by the physician.

###### **4.3 Contraindications:**

- Not applicable

###### **4.4 Special warnings and precautions for use:**

- This ointment is only to be applied topically to the skin.

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. If local irritation and hypersensitivity develop, then discontinue treatment.

#### **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 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**

No studies on the effects on the ability to drive and use machines have been performed.

#### **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.

### **5. Pharmacological properties**

#### **5.1 Pharmacodynamic properties**

##### **Mode of action**

Povidone-iodine is a complex of Iodine which retains the broad-spectrum germicidal activity of elemental iodine without its disadvantages. The germicidal activity is maintained in the presence of blood, pus, serum and necrotic tissue. Povidone iodine is an iodophore antiseptic and is a microbicidal drug. It releases iodine from its complex and produces pharmacological actions. The released iodine produces antiseptic actions. Iodine is highly reactive with surrounding and has strong oxidizing effect on functional groups of amino acids (-NH<sub>2</sub>, -SH etc.), Nucleotides, and fatty acids (double bond of unsaturated fatty acids). Interaction of Iodine with these groups in a cell results in disintegration of the cytoplasm, enzyme denaturation, loss of integrity in the bacterial cell membrane and fungal cell wall. These will lead to destruction of microbial protein and DNA and finally kills the microbes.

#### **5.2 Pharmacokinetic properties**

Absorption: Iodine is poorly absorbed through intact skin but absorption is enhanced through denuded skin.

Distribution: Widely distributed

Metabolism: Metabolized in liver by oxidation & glucuronide conjugation, Excretion: Excreted in urine

### **5.3 Preclinical safety data**

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction.

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

PEG 4000

PEG 400

Chlorocresol

### **6.2 Incompatibilities**

None

### **6.3 Shelf life**

3 years

### **6.4 Special precautions for storage**

Store in cool and dry place, at Temperature Not more than 30<sup>0</sup>C.

### **6.5 Nature and contents of container**

20 gm Collapsible tube

## **7. MARKETING AUTHORISATION HOLDER**

### **APPLICANT:**

**Jawa International Limited**

**Jawa House, Plot 6, Abimbola Way**

**Isolo Industrial Estate**

**Isolo Lagos, Nigeria**

### **MANUFACTURER:**

**Jawa International Limited**

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