

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

WOSAN MOUTHWASH

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

Povidone Iodine Mouthwash 1% w/v

## **3. PHARMACEUTICAL FORM**

Mouthwash

A deep brown coloured solution with peppermint odour.

## **4. CLINICAL PARTICULARS**

### **Therapeutic indications**

#### **For External Use Only**

It helps to prevent acute infections of the lining of the mouth and throat, for example, inflammation of the gums (gingivitis) and mouth ulcers. For cleansing the mouth (oral hygiene) before, during and after dental and mouth surgery.

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

For Oral administration. Apply directly as required

### **Contraindications:**

Hypersensitivity to iodine to any excipient. History of abnormal thyroid function or goitre (in particular nodular colloid goitre, endemic goitre and Hashimoto's thyroiditis).

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

For external use only.

Major wounds or perforations should be treated more dynamically.

May be harmful if swallowed. If infection or irritation develops, discontinue use and consult a doctor.

**KEEP OUT OF REACH OF CHILDREN.**

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

No interaction studies have been performed.

**Fertility, Pregnancy and lactation**

Can be used with care.

**Undesirable effects**

Skin redness have been reported rarely. None of serious effect shown.

**Overdose**

Not likely

**5. Pharmacological properties****Pharmacodynamic properties**

Antiseptic – Povidone Iodine is a complex of Iodine, which is chemically and physically stable and overcomes the problems due to volatility of elemental iodine. Povidone Iodine has a much-reduced oral toxicity and an almost negligible irritant orcorrosive effect on the skin compared with elemental iodine.

Povidone iodine is a microbial agent which acts on a wide variety of bacterial(including anaerobic and sporulated) organisms, fungi, protozoa and viruses.

**Pharmacokinetic properties**

Studies following Povidone iodine used as a surgical scrub, oral antiseptic and vaginalgel showed some absorption of iodine. Blood levels correlated well with urine levels resulting in excretion of excess iodine. Absorption causes an elevation of serumprotein bound iodine which returns to normal in 3 to 7 days if renal function is normal. Iodine is excreted by the kidneys.

**Preclinical safety data**

Not Applicable

**6. Pharmaceutical particulars****List of excipients**

Citric Acid

Glycerin

Peppermint Oil

Menthol crystals

Alcohol (absolute)

Purified water

**Incompatibilities**

None

**Shelf life**

3 years

**Special precautions for storage**

Do not store above 25°C protect from direct sunlight.

**Nature and contents of container**

100 ml white bottle with 28 mm cap

**7. MARKETING AUTHORISATION HOLDER**

**JAWA INTERNATIONAL LTD.**

Jawa House Compound,  
Plot 6 Abimbola Way,  
Isolo Industrial Estate,  
Isolo, Lagos, Nigeria

**Manufacturer:**

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