Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Iodine Tincture (Alcoholic Iodine Solution BP), Cutaneous Solution
Iodine 2.5% w/v
Potassium Iodide 2.5% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains Iodine 2.5% w/v and Potassium Iodide 2.5% w/v.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution.
Iodine Tincture is a brownish yellow liquid with a characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Antiseptic for minor cuts, wounds, and abrasions and unbroken skin.

4.2 Posology and method of administration

Not for use in children under 2 years (see section 4.3).

Clean the affected area. Apply topically using cotton wool. Do not cover with an occlusive dressing. Do not use for mor
two weeks. When the wound has begun to heal discontinue use. If the wound has not begun to heal in two weeks, discor
use and contact your doctor.

4.3 Contraindications

Do not use during pregnancy or lactation (see section 4.6).
Hypersensitivity to the ingredient iodine or any of the excipients.
Do not use on children under 2 years of age (see section 4.2).
Regular use is contraindicated for children and users with thyroid disorders (in particular nodular goiter). Do not use fo
prolonged periods.

4.4 Special warnings and precautions for use

Iodine may cause sensitivity reactions. For external use only. Product should not be ingested internally. Iodine stains the skin a deep reddish-brown. Do not apply to mucous membranes.

4.5 Interaction with other medicinal products and other forms of interaction

Interference with thyroid function tests has occurred. The effects of iodine and iodides on the thyroid may be altered by other compounds including amiodarone and lithium.

4.6 Pregnancy and lactation

Iodine should be avoided in cases of pregnancy or lactating women as absorbed iodine can cross the placental barrier and can be secreted into breast milk and could affect foetal thyroid function and development. Do not use during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

No adverse effects reported.

4.8 Undesirable effects

None reported

4.9 Overdose

In acute iodine poisoning copious draughts of milk and starch mucilage should be given and the stomach emptied by aspiration and lavage with dilute starch or a 1% solution of sodium thiosulphate. The use of gastric lavage with activated charcoal has also been suggested. Electrolyte and water losses should be replaced and circulation should be maintained.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Tincture of Iodine is used as a disinfectant and antiseptic. It has powerful bactericidal action. It is also active against fungi, viruses, protozoa, cysts and spores. Its activity is reduced in the presence of organic matter, though not to the same extent as with other halogen disinfectants.

5.2 Pharmacokinetic properties

Iodine is slightly absorbed when applied to the skin. When taken by mouth, iodine preparations which are converted to iodine and iodides are trapped by the thyroid gland. Iodides not taken up in the thyroid and excreted mainly in the urine with smaller amounts appearing in the faeces, saliva and sweat. They cross the placenta and are excreted in breast milk.

5.3 Preclinical safety data

No preclinical studies were carried out.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (90%)
Purified Water.

6.2 Incompatibilities

Iodine is incompatible with acetone, with which it forms an irritating compound. Incompatible with alkalis, alkali carbonates, alkaloids, ammonia, phenol, sodium thiosulphate, starch, tannins and vegetable astringents.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

30ml glass amber bottle with polypropylene tamper evident cap.
500ml dispensing pack glass amber bottle with a tamper evident cap.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Replace cap tightly when not in use.

7 MARKETING AUTHORISATION HOLDER

Ovelle Ltd
Industrial Estate
Coe's Road
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8 MARKETING AUTHORISATION NUMBER

PA 206/25/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th October 1992

Date of last renewal: 13th October 2007

10 DATE OF REVISION OF THE TEXT

October 2010