SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Alcoholic Iodine Solution BP

Iodine Tincture BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Iodine 2.5% w/v, Potassium Iodide 2.5% w/v

Excipients of known effect

Ethanol 85.4% v/v

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution.

Adark brown, clear, mobile liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an antiseptic for use on minor wounds, cuts and abrasions.

4.2 Posology and method of administration

For cutaneous use.

The product is suitable for use by adults, children and the elderly.

Apply to the affected part with cotton wool or a small brush.

4.3 Contraindications

Contraindicated for patients hypersensitive to iodine or iodides.

Contradicted for use in newborn infants.

Contradicted in patients with thyroid disorders or those receiving lithium therapy.

4.4 Special warnings and precautions for use

Avoid prolonged use.

For external use only.

Keep all medicines out of the sight and reach of children.

Solutions of iodine applied to the skin should not be covered with occlusive dressings, (otc packs to state the shortened warning, "DO NOT COVER").

Do not use on large, open wounds.

Highly flammable. Instruct patients to keep away from naked flames, lit cigarettes and some devices (e.g. hairdryers).

Ingredients with known effects

This medicine contains 85.4% v/v alcohol (ethanol) in each application. It may cause burning sensation on damaged skin.

4.5 Interaction with other medicinal products and other forms of interaction

Administration of this product may interfere with tests of thyroid function.

4.6 Pregnancy and lactation

Use with caution during pregnancy and lactation. Iodides cross the placenta and are excreted in breast milk.

4.7 Effects on ability to drive and use machines

None or negligible influence.

4.8 Undesirable effects

May cause allergic reactions, including urticaria, angioedema, cutaneous haemorrhage or purpuras, fever, arthralgia, lymphadenopathy and eosinophilia.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

4.9 Overdose

This product is not intended for internal use.

Symptoms of acute poisoning from ingestion of iodine include a disagreeable metallic taste, vomiting, abdominal pain and diarrhoea, thirst and headache may occur. The fatal dose of iodine is 2 to 3g. Symptomatic treatment for allergic reactions and iodism may be required, although symptoms usually subside rapidly when administration of iodine or iodide is stopped.

In acute poisoning copious draughts of milk and starch mucilage should be given.

Lavage should probably not be attempted and certainly not unless iodine had been ingested in sufficiently dilute form not to produce gastrointestinal corrosion. Other treatments include activated charcoal and sodium thiosulphate solution 1% or 5% to reduce iodine to the less toxic iodides. Electrolyte and water losses should be replaced and the circulation should be maintained. Pethidine or morphine sulphate may be given for pain, under medical supervision. A tracheotomy may become necessary.

Provided the product is not applied to large, open wounds or used for prolonged periods, clinically significant systemic absorption is unlikely. Systemic toxicity may lead to shock, tachycardia, fever, metabolic acidosis and renal impairment Death may be due to circulatory failure, oedema of the epiglottis resulting in asphyxia, aspiration pneumonia or pulmonary oedema. Oesophageal stricture may occur if the patient survives the acute stage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

D08A G03 - Antiseptics and disinfectants, iodine products

Iodine has a powerful bactericidal action and is used for disinfecting unbroken skin before operations. Iodine is active against fungi, viruses, protozoa, cysts and spores.

5.2 Pharmacokinetic properties

Iodine is only slightly absorbed when applied to the skin.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water

Ethanol (96%)

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months unopened

6.4 Special precautions for storage

Store below 25°C in a well closed container.

6.5 Nature and contents of container

25ml: Glass bottle with plastic lined cap

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

L.C.M. Ltd.,
Linthwaite Laboratories
Huddersfield
HD7 5QH

8 MARKETING AUTHORISATION NUMBER

PL 12965/0019

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25th August 1993

10 DATE OF REVISION OF THE TEXT

19/03/2020