# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Aqueous Iodine Oral Solution BP

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Iodine 5.0% w/v
Potassium Iodide 10.0% w/v

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Oral Solution

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic Indications

For use in the pre-operative management of hyperthyroidism.

### 4.2. Posology and Method of Administration

Oral.
Dose: adults, children and the elderly: 0.1 – 0.3ml well diluted in milk or water.
Dosage schedule: to be taken three times a day for six days.

### 4.3. Contra-Indications

Contraindicated for patients hypersensitive to iodine or iodides, and use in pregnancy and lactation.

## 4.4. Special Warnings and Special Precautions for Use

Should not be used for long term treatment.
Dispensing pack-not for retail sale.
Keep all medicines away from children.
Use with caution in children.

## 4.5. Interactions 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

Not to be used during pregnancy and lactation. Iodides cross the placenta and are excreted in
breast milk. There is a possibility of goitre in infants of mothers taking iodides.

## 4.7. Effects on Ability to Drive and Use Machines

None known.

## 4.8. Undesirable effects

May cause allergic reactions, including urticaria, angioedema, cutaneous haemorrhage or purpuras, fever, arthralgia, lymphadenopathy and eosinophilia, coryza-like symptoms, headache, lachrymation, conjunctivitis, laryngitis, bronchitis, and pain in the salivary glands. In addition to the above, use may lead to adverse effects on the mouth such as metallic taste, increased salivation, burning or pain. Swelling and inflammation of the throat, acneform skin disorders, depression, insomnia, impotence and diarrhoea (which may be bloody) can also result.

**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.

## 4.9. Overdose

Symptoms of acute poisoning from ingestion of iodine include a disagreeable metallic taste, vomiting, abdominal pain and diarrhoea may occur. Renal failure may occur 1-3 days later. Death may be caused by circulatory failure, swelling of the epiglottis causing asphyxia, aspiration, pneumonia or pulmonary oedema. Oesophageal stricture may occur if the patient survives the acute stage. 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. If there is no oesophageal damage the stomach may be emptied by aspiration and lavage with dilute starch mucilage or a 1% solution of sodium thiosulphate, Use of gastric lavage with activated charcoal has also been suggested. 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.

# 5. PHARMACOLOGICAL PROPERTIES

## 5.1. Pharmacodynamic Properties

Iodine and iodides are used in the pre-operative treatment of hyperthyroidism in conjunction with antithyroid agents. The patient is rendered euthyroid with an antithyroid agent and iodine or iodides are added to the therapy before subtotal thyroidectomy. Iodine aqueous solution is given to render the thyroid firm and avoid the increased vascularity and friability with increased risk of haemorrhage that may result from the use of an antithyroid agent alone.

## 5.2. Pharmacokinetic Properties

Iodine is converted to iodide, which is trapped in the thyroid gland.
Iodides are excreted mainly in the urine with smaller amounts excreted in the faeces, sweat and saliva. They cross the placenta and are excreted in breast milk.

## 5.3. Pre-clinical Safety Data

No data of relevance which is additional to that included on other sections of the SPC.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Purified water

### 6.2. Incompatibilities

None known.

### 6.3 Shelf Life

36 months unopened.

### 6.4. Special Precautions for Storage

Store below 25ºC.

### 6.5 Nature and contents of container

500ml Amber glass bottle, plastic cap.

### 6.6. Instructions for Use, Handling and Disposal

None.

## 7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd.,
Linthwaite Laboratories
Huddersfield
HD7 5QH

## 8. MARKETING AUTHORISATION NUMBER(S)

PL 00240/6170R

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

04/12/98

## 10 DATE OF REVISION OF THE TEXT

26/11/2014