Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Potassium Iodate 85mg Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 85mg Potassium Iodate, equivalent to 50mg of Iodine.

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
Off white, round tablet with star shaped double break line, engraved 2202 on the obverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Potassium Iodate is indicated as a thyroid blocking agent to prevent the uptake of radioactive iodine following a nuclear accident.

4.2 Posology and method of administration

For oral administration.

Administration should take place within 3 hours of a nuclear accident or up to 10 hours after an accident, however, this is less effective.

A single daily dose should be administered. Repeated daily administration is necessary in situations involving prolonged exposure. However, pregnant and lactating women should ordinarily receive not more than two doses and neonates not more than one dose.

	Tablets	Iodine equivalent
Adults and adolescents (over 12 years)	2 tablets	100 mg
Children (3-12 years)	1 tablet	50 mg
Children (1 month – 3 years)	½ tablet	25 mg
Neonates (birth – 1 month)	¼ tablet or 12.5mg iodine equivalent as standard solution	12.5mg

For neonates over 1 week of age living at home, a dosage of a ¼ tablet is satisfactory. For neonates less than one week of age a more exact dosage of 12.5 mg iodine equivalent should be given as a standard solution freshly prepared from KI crystals. It is recommended that maternity wards store KI crystals.

For children the tablet dose may be crushed and mixed with mild or water before administration.

Elderly

The recommended adult dose is appropriate.

4.3 Contraindications

Potassium Iodate is contra-indicated in patients with known iodine sensitivity, renal failure, hypocomplementaemic vasculitis or dermatitis herpetiformis.

4.4 Special warnings and precautions for use

In cases of exposure to radioiodine from nuclear accidents, dosing of potassium iodate should be based on emergency plans and predetermined operational intervention levels. Risk benefit of administration of stable radioiodine should be considered for the different age groups at risk. A single dose of potassium iodate gives adequate protection for one day. Prolonged exposure may require repeat dosing. Iodine prophylaxis protects only against inhaled or ingested radioiodine and should be used in conjunction with other counter measures (e.g. evacuation, sheltering, food control).

Patients with thyrotoxicosis treated medically, or patients with a past history of thyrotoxicosis treated medically who are now off treatment and apparently in remission, may be at risk.

Iodine induced hyperthyroidism may be precipitated in patients with asymptomatic nodular goitre or latent Graves` disease, who are not under medical care.

Potassium salts should be given cautiously to patients with renal or adrenal insufficiency, acute dehydration or heat cramp.

Care should be exercised if potassium salts are given concomitantly with potassium-sparing diuretics, as hyperkalaemia may result.

Potassium Iodate prophylaxis is not indicated in adults over 40 unless doses to the thyroid from inhalation rise to levels threatening thyroid function that is of the order of about 5 Gy. The risk of thyroid cancer is extremely low in this group whereas the incidence of thyroid disease is higher in this group therefore the risk of iodine induced thyroid complications are higher.

The potential benefit of iodine prophylaxis is greatest in the young. The thyroid of the foetus, neonate and young infant has a higher yearly thyroid cancer risk per unit dose of radioactive iodine than the thyroid of an adult.

Neonates in the first days of life are at particular risk from exposure to radioactive iodine and blocking of thyroid function by overload of potassium iodate. The fraction of radioactive uptake is fourfold greater than all other age groups. The neonatal thyroid is especially sensitive to functional blocking caused by overload of potassium iodate. Transient hypothyroidism during the early period of brain development can result in loss of intellectual capacity. If stable iodine is given to neonates close follow up of thyroid function is essential. For neonates who have been administered potassium iodate in the first few weeks of life TSH levels and, if necessary, T4 levels should be monitored and appropriate replacement therapy given.

4.5 Interaction with other medicinal products and other forms of interaction

Several drugs, such as captopril and enalopril can induce hyperkalaemia and this effect may be enhanced if Potassium Iodate is also administered.

The effect of quinidine on the heart is increased by increased plasma concentrations of potassium.

Hyperkalaemia results from the interaction between potassium salts and potassium sparing diuretics such as amiloride or triamterene or aldosterone antagonists.

4.6 Pregnancy and lactation

Teratogenic effects such as congenital goitre and hypothyroidism have been reported when iodides, and therefore presumably iodate, are administered to pregnant women.

However, in the event of a nuclear accident, the proper use of Potassium Iodate in low doses, over a short period of time, as a thyroid blocking agent is not contra-indicated. Prophylactic administration of iodate to the pregnant mother should also be effective for the foetus.

Throughout pregnancy the number of doses of potassium iodate should be kept to a minimum.
In areas of iodine deficiency prolonged dosage could lead to maternal or fetal thyroid blockage with possible consequences for foetal development.

If potassium iodate is administered late in pregnancy, the thyroid function of the new-born should be monitored. This is generally met by routine screening in the neonatal period. For neonates who have been administered potassium iodate in the first few weeks of life TSH levels and, if necessary, T4 levels should be monitored and appropriate replacements therapy given.

Pregnant women with active hyperthyroidism must not take potassium iodate because of the risk of foetal thyroid blockage. Pregnant women and neonates should not receive repeat doses of potassium iodate.

Iodine is actively transported to the milk. As much as a quarter of the iodine taken by the mother may be secreted in the milk within 24 hours. Potassium iodate can partially block transport of radioiodine in the milk. The same criteria should apply when selecting a dose of potassium iodate to protect a lactating mother as that used for other young adults under 40 years of age.

4.7 Effects on ability to drive and use machines

No effect.

4.8 Undesirable effects

Since experience with Potassium Iodate is limited, presumably the following side effects which can occur with potassium iodide can also be associated with Potassium Iodate.

Hypersensitivity reactions such as skin rashes, swollen salivary glands; headache, bronchospasm and gastro-intestinal disturbances can be mild or severe and may be dose dependent.

Retinal toxicity has been associated with potassium iodate overdose. Hyperthyroidism, iodine induced autoimmunity (Grave's and Hashimoto type), toxic nodular goitre, iodine-induced hypothyroidism and an increase of papillary cancers have been reported as side effects of iodine therapy.

Continued administration may lead to mental depression, nervousness, sexual impotence and insomnia.

4.9 Overdose

In overdose, symptoms or iodism, such as headache, pain and swelling of the salivary glands, fever or laryngitis, swelling or inflammation of the throat, gastrointestinal upset and diarrhoea can occur. Pulmonary oedema can also occur.

Acute ingestion of iodine can result in corrosive injury of the gastrointestinal tract and renal damage. Cardiopulmonary collapse due to circulatory failure should be treated by maintenance of airway and stabilisation of the circulation. Oedema of the glottis resulting in asphyxia or aspiration pneumonia can occur.

In acute iodine poisoning large quantities of milk and starch mucilage have been given.

Lavage with starch mucilage or lavage with activated charcoal should be considered if there is no oesophageal damage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: V03A B21, Antidotes
The iodine released from iodide and iodate on absorption from the gut is taken up rapidly and preferentially by the cells of the thyroid gland. Once in the thyroid, it is rapidly incorporated into organic molecules that are synthesised into thyroid hormones and ultimately released into the general circulation.

If excessive amounts of stable iodate are administered to normal adults, the iodine uptake mechanism of the thyroid is saturated and little or no further iodine is taken up. This effectively blocks the uptake of radioactive iodine in the event of accidental exposure to radioiodines.

5.2 Pharmacokinetic properties

Iodine absorbed from the gut is taken up rapidly and preferentially by the cells of the thyroid gland. Renal clearance of iodide/iodate is usually in the range of 30 to 50 ml of serum/minute, is closely related to glomerular filtration, and is little affected by the iodate load. Most radioiodine not taken up by the thyroid gland after a single oral bolus of iodate is excreted in the urine over the subsequent 48-hour period.

5.3 Preclinical safety data

Preclinical information has not been included because the safety profile of Potassium Iodate has been established after many years of clinical use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium hydrogen phosphate
Croscarmellose sodium
Microcrystalline cellulose
Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

Polypropylene containers: 2 years
PVC/PVDC/Al Blisters: 2 years

6.4 Special precautions for storage

Do not store above 25°C.
Store in original container.

6.5 Nature and contents of container

In polypropylene containers with HDPE caps or child resistant closures in packs of 50, 100, 500 or 1000 tablets. PVDC Blister packs with aluminium foil in pack sizes of 6, 10 or 100 tablets.
Not all pack sizes may be marketed.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 0943/019/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 17 April 2008

10 DATE OF REVISION OF THE TEXT

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