SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Potassium iodide G.L. Pharma 65 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains 65 mg potassium iodide, equivalent to 50 mg iodine.

Excipient with known effect:
1 tablet contains 80 mg lactose monohydrate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet
Diameter: about 8.3 mm
Thickness: 3.2-3.8 mm

White to brown-white, round, curved tablet with a pressure-sensitive cross break line on the inner side and notches on the outer side.
The tablet can be divided into equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Potassium iodide G.L. Pharma is indicated for the use after nuclear accidents with release of radioactive iodine isotopes to prevent the uptake of radioactive iodine in the thyroid after intake or inhalation of this substance.

4.2 Posology and method of administration

Iodine tablets may only be taken after explicit appeal by the authority, for example via radio or television.

Timing of administration
It is recommended to use the tablets as soon as possible and preferably within 2 hours after the expected onset of exposure. However, an administration up to 8 hours after the estimated onset of exposure is still useful.

Posology

Adults and children above 12 years:	100 mg iodine (2 tablets)
Children from 3 to 12 years:	50 mg iodine (1 tablet)

Children from 1 month to 3 years: 25 mg iodine (½ tablet)
Newborns and babies younger than a month: 12.5 mg iodine (¼ tablet)
Pregnant and breast-feeding women (all ages): 100 mg iodine (2 tablets)

Duration of administration
A single administration is usually sufficient.

If the release of radioactive iodine continues (> 24 hours), with repeated exposure, intake of contaminated food or drinking water and if evacuation is not possible, a repeated administration may be necessary.

Special populations
Neonates, pregnant and breast-feeding women and older adults (> 60 years) should not receive more than one dose (see section 4.6). Neonates and older people (> 60 years) are at higher risk of adverse health effects if they receive repeated doses of stable iodine (see sections 4.4 and 4.6).

Adults above 40 years of age
The intake of iodine tablets is not recommended for persons above 40 years because they are less likely to benefit from treatment with iodine tablets after exposure to radioactive iodine (see section 4.4).

Hepatic and renal impairment
No dosage adjustments are required in special populations such as patients with impaired renal or hepatic function. Iodine elimination occurs mainly via the kidneys; however, renal elimination rate is not influenced by iodine intake or iodine serum levels.

Method of administration
Oral use.
The tablets may be chewed or swallowed whole.

Paediatric population
To be able to provide the proper doses for children more easily, the tablets have got a cross break score. For newborns and babies, the dose may be ground or dispersed in water, syrup or a similar liquid. It may take up to 6 minutes until the tablets are fully dispersed.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Dermatitis herpetiformis van Dühring
- Hyperthyroidism
- Hypocomplementaemic vasculitis

4.4 Special warnings and precautions for use

Iodine prophylaxis protects against inhaled or ingested radioiodine and has no effect on other ingested radionuclides.

If thyroid carcinoma is suspected, iodine administration should generally be avoided.
The administration of iodine interferes with radioiodine therapy and thyroid diagnostics.

Patients undergoing thyreostatic treatment must continue with such therapy and regularly undergo medical examinations at short intervals.

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.

The risk of iodine induced hyperthyroidism may be increased in patients with asymptomatic nodular goitre or latent Graves` disease, who are not under medical care.

Pharmacological doses of iodine may cause thyroid enlargement, which in turn may aggravate airway constriction.

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.

In cases of exposure to radioiodine from nuclear accidents, dosing of potassium iodide should be based on emergency plans and predetermined operational intervention levels. Risk benefit of administration of stable iodine should be weighed for the different age groups at risk.

The groups most likely to benefit from treatment with iodine tablets after exposure to radioactive iodine are children, adolescents, and pregnant and breast-feeding women as well as people living in iodine deficient areas (who are more likely to be affected by exposure to radioactive iodine). If the supply of stable iodine is limited, priority should be given to children and younger adults.

Adults over 40 years of age are less likely to benefit from treatment with iodine tablets after exposure to radioactive iodine. However, individuals at risk of exposure to high doses of radioactive iodine (e.g. emergency workers involved in rescue or clean-up operations) are likely to benefit from treatment, irrespective of their age and should be given priority.

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 iodide. The fraction of radioactive uptake is fourfold greater than in all other age groups. The neonatal thyroid is especially sensitive to functional blocking caused by overload of potassium iodide. Transient hypothyroidism during this 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 iodide in the first few weeks of life TSH levels and, if necessary, T4 levels should be monitored and appropriate replacement therapy given.

This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Iodine administration interferes with radioiodine therapy and thyroid diagnostics (see section 4.4).
Several drugs, such as captopril and enalapril can cause hyperkalaemia and this effect may be enhanced if potassium iodide is also administered.

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

Potassium salts given concomitantly with potassium-sparing diuretics such as amiloride or triamterene or aldosterone antagonists may cause hyperkalaemia (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy
Repeated administration of iodine during pregnancy may suppress foetal thyroid function. Reproductive toxicity has been established in animal studies. Therefore, pregnant women should not receive more than one dose (see section 4.2). If iodine is taken in late pregnancy it is recommended to monitor the thyroid function of the newborn.

Breast-feeding
Iodine is being excreted into breast milk in large amounts, but these amounts are too small to protect the baby sufficiently. Thus, the baby has to be given iodine tablets as well. If the intake during breast-feeding is necessary, breast-feeding women should not receive more than one dose (see section 4.2).

Fertility
In rats, fertility is unaffected up to iodine dose of 150 mg/kg (see section 5.3). No human data on fertility are available.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Very common (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1,000 to < 1/100)
Rare (≥ 1/10,000 to < 1/1,000)
Very rare (< 1/10,000)
Not known (cannot be estimated from the available data)

Immune system disorders	
Not known	Hypersensitivity reactions such as swollen salivary glands, headache, bronchospasm and gastro-intestinal disturbances can be mild or severe and may be dose dependent.
Endocrine disorders	
Not known	Iodine-induced autoimmunity (Grave's and Hashimoto type), toxic nodular goitre and iodine-induced transient hyper- or hypothyroidism have been reported as side effects of iodine therapy. An overactive thyroid gland, thyroiditis, and an enlarged thyroid gland with or without development or myxoedema have also been reported.
Psychiatric disorders	
Not known	Continued administration may lead to mental depression, nervousness, sexual impotence and insomnia.
Gastrointestinal disorders	
Not known	Sialadenitis, gastrointestinal disturbances
Skin and subcutaneous tissue disorders	
Rare	Temporary skin rash

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 national reporting system:
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

4.9 Overdose

Symptoms
In overdose, symptoms of 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 should be given.

Newborns are particularly sensitive to iodine overload, probably by an immature regulation system. For neonates who have been administered potassium iodide in the first few weeks of life TSH levels and, if necessary, T4 levels should be monitored and appropriate replacement therapy given (see also section 4.4).

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

Electrolyte and water losses should be replaced and the circulation should be maintained. Pethidine (100 mg) or morphine sulphate (10 mg) may be given for pain. A tracheostomy may become necessary.

Haemodialysis may reduce excessively elevated serum iodine concentrations.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antidotes, ATC code: V03AB21

In cases of a nuclear accident radioactive iodine may form a large amount of the output. Because of its high volatility it can be easily inhaled and absorbed via the lungs.
Radioactive iodine can be detected in large amounts in the thyroid if exposed to very strong radiation, by which the risk for local damage is increased. The uptake of radioactive iodine by the thyroid can be blocked by saturation, by the early intake of a high dose of stable iodide. A dose of 130 mg (= 2 tablets) potassium iodide provides complete saturation. The risk for thyroid cancer due to exposition to radioactive iodine is higher in younger persons. Generally it is assumed that foetuses of more than 12 weeks, newborns and children have got the highest risk because their thyroid is still in growth.

5.2 Pharmacokinetic properties

Absorption
Orally administered iodine is converted in inorganic iodide and it is almost completely absorbed from the gastrointestinal tract. Food causes a delay of 10-15 minutes. Absorption is completed 2 hours after oral administration.
At intake on an empty stomach, radioactive ^{131}I is detected in the neck area after about 3 minutes.
Physiological serum concentrations in humans vary from 1-5 µg/l (40 to 80 nmol/l) at daily iodine intakes of 150-250 µg.

Distribution
Iodine in the systemic circulation is being exchanged rapidly between erythrocytes and extracellular liquid. The total amount of inorganic iodide in this pool is about 250 µg.
The uptake of iodide by the thyroid depends on volume, thyroid function, plasma iodide concentration and physiological age. Active iodide transport in extrathyroidal tissues such as salivary gland, lacrimal gland, choroid plexus, ciliary body of the eye, skin, placenta, gastric mucosa, and in mammary glands during lactation takes place to a minor extent.

Iodine passes the placental barrier and is taken up by the foetal thyroid. It was found that uptake starts around a foetal age of 3 months. The highest concentration was found at a foetal age of about 6 months. In children and adolescents the iodine uptake by the thyroid is higher than in adults. In elderly persons, however, a significant reduction was observed.

If iodine doses are administered on an empty stomach, the half maximum thyroid uptake is reached after approximately 4 hours, although the duration is between 2.5 and 6.5 hours for most of the patients.

Biotransformation
Iodine undergoes organification in the thyroid, i.e. it is being oxidized and linked to thyroglobuline. The thyroid hormones thyroxine (T4) and triiodothyronine (T3) are being synthetized via oxidative condensation of the iodated intermediates monoiodotyrosine (MIT) and diiodotyrosine (DIT) inside the thyroglobuline complex. Hormone secretion takes place by way of pinocytosis followed by proteolytical release of T4 and T3 from thyroglobuline.

Elimination
The main elimination (95%) occurs via the kidneys and amounts for approximately 30-40 ml/min.
Renal elimination rate is not influenced by iodine intake or iodine serum levels.
In pregnant women there is an increased elimination of iodide which may cause iodine deficiency.
Only small amounts of iodine have been found in faeces (approximately 1% of the total iodine elimination).
Iodine is being excreted into breast milk in considerable amounts (10-15% of the intake).

5.3 Preclinical safety data

A single administration of high doses (333-1,667 mg/kg) has been found to be teratogenic in rats. In another study in rats, the administration of high daily iodine doses led to incomplete parturition, failure of lactation and reduced mothering activities. In rabbits, iodine intake (250 mg/kg) led to increased offspring mortality. The administration of an iodine-containing substance to pigs and hamsters had no teratogenic effects.
In a long-term study where rats received potassium iodide in the drinking water for two years (total intake 38,609 mg/kg), the development of squamous cell carcinomas in the salivary glands was observed.
No evidence of mutagenic potential has been established for potassium iodide.
Effects in the non-clinical reproductive study were observed, but only at exposures considered sufficiently in excess of the maximum human dosage (100, 300, and 500 mg/300 g in rats), indicating little relevance to clinical use for the single dose therapy.

Apart from the information provided in the other sections, there is no additional relevant information from animal studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Lactose monohydrate
Microcrystalline cellulose
Basic butylated methacrylate copolymer

Magnesium stearate (E 572)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

7 years

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

Blister packs: PVC-PVdC/aluminium blister containing 2, 4, 6, 10, and 20 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach, Austria

8. MARKETING AUTHORISATION NUMBER

MA993/00101

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17.02.2014

10. DATE OF REVISION OF THE TEXT

09/2024