

This is a special medicinal product to be taken in the event of radiation accidents with release of radioactive iodine.
May only be taken on the explicit direction of a doctor or relevant authorities.

This medicinal product must not be taken in the event of:

- hyperthyroidism,
- known hypersensitivity to iodine or one of the other components of the product,
- dermatitis herpetiformis (Duhring's disease),
- hypocomplementaemic vasculitis.

Please read the following medical information carefully. It is important and must be observed when using this product. Consult your doctor or pharmacist if you have any queries.

Information

Potassium Iodide "Lannacher" 65 mg tablets

Active ingredient: potassium iodide

Composition

Pharmaceutically active ingredient:

1 tablet potassium iodide "Lannacher" contains 65 mg potassium iodide equivalent to 50 mg iodide.

Excipients:

Maize starch, lactose monohydrate, microcrystalline cellulose, Poly[butylmethacrylate-co-(2-dimethylaminoethyl) methacrylate-co-methylmethacrylate] (1:2:1) (Eudragit E100), magnesium stearate (Ph.Eur.) [plant origin].

Pharmaceutical Form and Contents

Potassium iodide "Lannacher" 65 mg tablets are available in packets of 20 tablets and 500 x 6 tablets.

Mode of Action

In the event of accidents in nuclear facilities, particularly nuclear power plants, release of radioactive iodine may occur under unfavourable circumstances. Radioactive iodine has the same chemical and biological properties as natural iodine found in diet and is therefore stored in the thyroid like normal non-radioactive iodine.

When taken at the appropriate dose, potassium iodide "Lannacher" 65 mg tablets saturate the thyroid with iodine. The uptake of radioactive iodine into the thyroid is thus prevented (so-called iodine blockade). This type of iodine tablet is not suitable for countering the effects of iodine deficiency found in Germany.

Pharmaceutical Manufacturer

Lannacher Heilmittel Ges.m.b.H.,
Schlossplatz 1, A-8502 Lannach, Austria

Therapeutic Indications

Potassium iodide "Lannacher" 65 mg tablets are used for blocking iodine in the event of nuclear accidents.

In the event of risk of harmful exposure to radioactive iodine, the authorities would give information through the media, together with information regarding provision of potassium iodide tablets and the duration of administration.

Contraindications

When should potassium iodide "Lannacher" 65 mg tablets not be taken?

You should not take potassium iodide "Lannacher" 65 mg tablets if you have:

- hyperthyroidism,
- known hypersensitivity to iodine (this is very rare and should not be confused with the frequent allergies experienced towards X-ray contrast agents) or to one of the other components of the product,
- dermatitis herpetiformis (Duhring's disease),
- hypocomplementaemic vasculitis (allergic inflammation of the blood vessel walls).

What precautions should be observed during pregnancy and lactation?

If you are pregnant or lactating, you should take the same dose as young adults and adults. The duration of administration for pregnant or lactating women should be restricted to 2 days (see dosage instructions).

If you are pregnant you should inform your doctor that you are taking iodine so the subsequent medical checks on the infant's thyroid function can be carefully monitored.

Are particular precautions required for people over 45 years old?

Iodine blocking is **not** recommended for people over 45 years old for two reasons:

1. There are iodine-deficient areas in Germany which means metabolic disturbances affecting the thyroid are more frequent with increasing age. This thyroid functional autonomy increases the risk of undesirable effects following iodine blockade.
2. The risk of malignant thyroid tumour caused by radiation sharply decreases with increasing age.

Precautions for Use and Warnings

What precautions should be observed?

Administration of high doses of iodine may cause an increase in the size of the thyroid, which will aggravate existing constriction of the windpipe.

In cases where there are untreated, uncontrolled hormone-forming sites ("hot" nodes), there is a risk of overproduction of thyroid hormones, which in severe cases can lead to life-threatening cardiovascular conditions. People affected by these conditions should therefore not take potassium iodide tablets.

People undergoing treatment with thyroid inhibitors (thyreostatics) due to hyperthyroidism, must continue their treatment and be medically monitored at frequent intervals.

Administration of iodine should be avoided if malignant thyroid tumours are suspected.

The administration of iodide in large quantities may make it impossible to carry out planned radioiodine therapy. Diagnostic tests of thyroid function may also be affected and provide incorrect results. This is particularly the case for thyroid scans (scintigrams) and studies of iodine metabolism, and for the TRH test.

What precautions should be taken if driving, operating machines or working without secure footing?

Adverse effect on concentration or reaction ability due to potassium iodide are not expected.

Interactions

What other medicinal products affect the action of potassium iodide "Lannacher" 65 mg tablets?

Substances affecting thyroid metabolism (e.g. perchlorate, thiocyanate at concentrations over 5 mg/dl) inhibit uptake of iodine by the thyroid.

What other medicinal products are affected in their action by potassium iodide "Lannacher" 65 mg tablets?

Potassium iodide "Lannacher" 65 mg tablets inhibit the action of thyroid inhibitors (thyreostatics).

Please note that this information may also apply for short-term use of the product.

Dosage and Method of Administration

The following information applies if your doctor has not prescribed alternative directions for the use of potassium iodide "Lannacher" 65 mg tablets.

Please follow the instructions carefully, otherwise the potassium iodide "Lannacher" 65 mg tablets may not act properly!

What quantity and how often should potassium iodide "Lannacher" 65 mg tablets be taken?

Population /age group

Dosage

Pregnant and lactating:	2 tablets	(equivalent to 100 mg iodide)
< 1 month:	¼ tablet	(equivalent to 12.5 mg iodide)
1 to under 36 months:	½ tablet	(equivalent to 25 mg iodide)
3 to under 13 years:	1 tablet	(equivalent to 50 mg iodide)
13 to under 45 years:	2 tablets	(equivalent to 100 mg iodide)
Persons over 45 years:	tablets not recommended to be taken	

A single administration is usually sufficient. In isolated cases the competent authorities or doctor may recommend a further administration of tablets.

Administration of tablets to neonates should always be restricted to 1 day, administration of tablets to pregnant and lactating women should be restricted to 2 days.

Splitting the tablets

Place the convex tablet on a hard surface (bevelled edges uppermost).

Dividing in half: press down on the edges of the tablet with two fingers.

Dividing into quarters: press one finger on the middle of the tablet.

How and when should potassium iodide "Lannacher" 65 mg tablets be taken?

To maintain the correct dosage for children under 36 months, the tablets should be divided using the notches. The tablets may be taken whole or dissolved in a little liquid. Possible irritation of the stomach lining can be avoided by drinking copious amounts of water.

Please only take the product following express direction of the competent authorities.

Protection is most effective if potassium iodide "Lannacher" 65 mg tablets are taken shortly before or at the same time as inhaling radioactive iodine. Later ingestion reduces possible protection. First administration of potassium iodide "Lannacher" 65 mg tablets should in any case not occur later than one day after inhalation or ingestion of radioactive iodine, since late use is more likely to be harmful.

Wrong Dosage and Overdose

Ingestion of large quantities of iodide may cause irritation of skin and mucosa and stomach ache. The symptoms generally resemble the undesirable effects described below. Medical attention should be sought if there is considerable discomfort.

Undesirable effects

What adverse effects may occur when potassium iodide "Lannacher" 65 mg tablets are taken?

Irritation of the stomach lining may occur, particularly if potassium iodide "Lannacher" 65 mg tablets are taken on an empty stomach.

When potassium iodide "Lannacher" 65 mg tablets are used to prevent storage of radioactive iodine, iodine-provoked hyperthyroidism may occur in isolated cases. Conditions such as increased pulse rate, perspiration attacks, sleeplessness, trembling, diarrhoea and loss of weight in spite of increased appetite may be indications of hyperthyroidism. You should consult your doctor if any of these conditions occur.

When taking iodine tablets for the first time, an unknown iodine allergy may occur in isolated cases. Allergic conditions such as reddening of the skin, itching and burning in the eyes, head cold, dry cough, diarrhoea and headache, among other symptoms, may occur. Particularly in the case of existing dermatitis herpetiformis (Dühring's disease), life-threatening reactions are possible; inflammation of blood vessels (e.g. polyarteritis nodosa) may occur.

If you notice any adverse effects which are not mentioned in this package insert, please inform your doctor or pharmacist.

Information on shelf life of the product

A slight brown discoloration of the tablets has no effect on either the action or tolerability of the medicine.

Keep the medicine out of the reach of children.

Store the tablets in their original packing at between 5 °C and 25 °C.

Keep the tablets in their original packing to protect the contents from light and moisture.

Date of revision of the text

November 2003