

Informed consent for the intake of potassium iodide tablets

Dear Parents and Legal Guardians!

The Chernobyl nuclear power plant accident has led to a significant escalation in the incidence of radiation-induced thyroid cancer in children and adolescents living in areas surrounding Chernobyl that were severely contaminated in the aftermath of the accident. The cause for that is the radioactive iodine, which is released in significant quantities upon such acute nuclear reactor accidents. After its absorption into the body, it is stored in the thyroid gland and induces a high level of radiation exposure in that region.

Taken early enough, the potassium iodide tablets saturate the thyroid gland with stable iodine and thus help prevent the storage of the radioactive iodine. Thereby the chances of radiation exposure of the thyroid gland and the resultant occurrence of radiation-induced thyroid cancer are practically reduced to zero. That requires, however, that the tablets be taken before the arrival of the radioactive clouds.

Intake of the potassium iodide tablets in a timely manner offers a vastly effective protection from the radiation-induced thyroid cancer.

In order to facilitate the intake of the tablets in a timely manner, supplies of potassium iodide tablets are being made available to schools and boarding schools. But your child can avail of it only with your prior permission. By signing the informed consent form below you will facilitate that availability to your child.

In the event of a nuclear reactor accident, the potassium iodide tablet shall be dispensed with only as per the express requirements stipulated by the public health authorities.

Please carefully read the enclosed information taken from the product insert for potassium iodide tablets.

The School Directorate

INFORMED CONSENT

Name of the child: _____ Date of birth: _____ Name of the legal guardian: _____

YES, I hereby issue my consent (for the duration of the stay at the facility) to administer the potassium iodide tablets to my child in compliance with the stipulations of the public health authorities. I confirm that I am unaware of any intolerances and contraindications for intake of the tablets and that I shall inform the school without undue delay should I receive intimation of such intolerances and contraindications.

NO, I do not offer my consent.

Date: _____

Signature: _____

Information on the potassium iodide tablets (analogous to the product insert)

Potassium iodide tablets may not be ingested:

- where symptoms of **thyroid hyperactivity** exist
- in the case of **benign nodules in the thyroid gland** that cannot be treated. With the so-called untreated “hot thyroid nodules” the danger of a massive overproduction of thyroid hormones persists, so that in the worst case it could trigger a life-threatening cardiovascular reaction.
- where there is cause to suspect **malignant tumor of the thyroid**. Thyroid tumors are treated with radioactive iodine. Potassium iodide tablets, when taken in large quantities, hinder the treatment of the tumor.
- in the case of **allergy** (oversensitivity) to iodine. That occurs in rare cases and cannot be mistaken for the frequently prevalent allergy to contrast agents (facilitating enhanced display of the different organs in the imaging process, such as x-ray diagnostics).
- in the case of **allergy** to one or the other components of the tablets (cornstarch, lactose monohydrate, microcrystalline celluloses, butyl methacrylate – copolymer, magnesium stearate)
- in the case of **duhring dermatitis herpetiformis** (a disease marked by occurrences of blisters, erythema (reddened skin), skin rashes, wheals, and acute burning itching, mostly on the elbows and knees
- in the case of allergy-induced **inflammation of the vascular walls** (hypocomplementamia vasculitis).

Particular caution must be exercised in the intake of potassium iodide tablets::

- In the case of a disease affecting the **trachea**. Administering high quantities of iodine can lead to the enlargement of the thyroid, which would further deteriorate the already prevalent constriction of the trachea.
- where **thyroid inhibitors** are administered to your child (**thyrostatics**). Please ask your physician if your child may take potassium iodide tablets.

Intake of potassium iodide tablets with other pharmaceutical remedies

– Impact of potassium iodide tablets is influenced by:

Remedies that impact on thyroid metabolism (e.g. perchlorate, thiocyanate in concentration over 5mg/dl). They inhibit the absorption of iodine by the thyroid.

–Potassium iodide tablets influence the impact on:

Thyroid inhibitors (thyrostatics)

What are some possible side-effects?

Like all remedies, even potassium iodide may generate side effects that may not necessarily occur in every instance. In the assessment of the side-effects, the following frequency distribution constitutes the basis:

- **very frequent** (they occur in more than 1 out of 10 patients)
- **frequent** (they occur in more than 1 out of 100 patients, but in less than 1 out of 10 patients)
- **occasional** (they occur in more than 1 out of 1000 patients and in less than 1 out of 100 patients)
- rarely** (they occur in more than 1 of 10,000 cases, but in less than 1 out of 1,000 patients)
- **very rarely** (they occur in less than 1 out of 10,000 patients)

Gastro-intestinal diseases

An irritation of the gastric mucosa can occur particularly upon the intake of potassium iodide tablets on empty stomach.

Hormonal diseases

Very rare: iodine-induced thyroid hyperactivity. Indications of a thyroid hyperactivity may include increased pulse rate, breaking into a sweat, insomnia, shakiness, diarrhea and loss of weight despite increased appetite.

Vascular diseases

Rare: Vascular inflammation (e.g. periarteritis nodosa)

Immune system disorders

Rare: An unknown iodine allergy may occur for the first time. Thereby allergic reactions such as reddening of the skin, itchiness and burning in the eyes, common cold, nervous cough, diarrhea, headache and similar symptoms may also occur. Particularly in the event of pre-existing duhring dermatitis herpetiformis (a disease wherein blisters and erythema may occur, especially in the elbows and knees) life-threatening reactions are possible (see above: potassium iodide tablets may not be taken).

Rule of thumb:

Please contact your physician or your pharmacist in case you have further questions or need advice.