**Package leaflet: Information for the user**

**Potassium iodide G.L. Pharma 65 mg tablets**
Potassium iodide

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Potassium iodide G.L. Pharma is and what it is used for
2. What you need to know before you take Potassium iodide G.L. Pharma
3. How to take Potassium iodide G.L. Pharma
4. Possible side effects
5. How to store Potassium iodide G.L. Pharma
6. Contents of the pack and other information


## 1. What Potassium iodide G.L. Pharma is and what it is used for

Potassium iodide is used in cases of nuclear accidents or nuclear reactor accidents to prevent the uptake of radioactive iodine by the thyroid.

In the event of nuclear reactor accidents, there may be an emission of radioactive iodine. In case of contamination, the radioactive iodine is taken up by the thyroid. The uptake of radioactive iodine by the thyroid is prevented by the intake of non-radioactive iodine (e.g. in the form of potassium iodide) before or during the contamination.

## 2. What you need to know before you take Potassium iodide G.L. Pharma

**Do not take Potassium iodide G.L. Pharma**
- if you are allergic to potassium iodide or any of the other ingredients of this medicine (listed in section 6).
- if you have an autoimmune disease involving itching and blisters of your skin (dermatitis herpetiformis van Dühring).
- if you have an overactive thyroid producing too much of thyroid hormones (hyperthyreosis).
- if you have a certain disorder of your blood vessel walls (hypocomplementaemic vasculitis).

**Warnings and precautions**
Talk to your doctor or pharmacist before using Potassium iodide G.L. Pharma if you:
- have a malign tumor in your thyroid or if your doctor assumes that you have one.
- have a narrowing of your wind-pipe (causing respiratory problems). The use of Potassium

iodide G.L. Pharma may worsen this condition.
- are being treated or were treated in the past for a thyroid problem.
- have a specific problem with your thyroid called thyroid autonomy and are not being treated for it.
- have problems with your kidneys.
- have problems or are being treated for problems with your adrenal glands.
- are suffering from dehydration or cramp due to extreme heat.
- are taking any of the medicines listed in section “Other medicines and Potassium iodide G.L. Pharma”.

**Children**
Babies until a few weeks of age should be taken to the doctor as soon as possible after being given Potassium iodide G.L. Pharma so that their thyroid function can be closely monitored.

**Other medicines and Potassium iodide G.L. Pharma**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Please remember that this information can also be applicable to medicines which you have taken/used recently.
Tell your doctor if you are taking:
- medicines inhibiting the thyroid function; when taken concomitantly with Potassium iodide G.L. Pharma you should be closely monitored by a doctor.
- captopril or enalapril; these medicines may cause an increased potassium level in your blood.
- quinidine; the effect of quinidine on the heart is increased by Potassium iodide G.L. Pharma.
- potassium-sparing diuretics (“water tablets”) such as amiloride or triamterene; those medicines may cause an increased potassium level in your blood.

The use of Potassium iodide G.L. Pharma may influence radioiodine therapy and the results of thyroid tests.

**Pregnancy and breast-feeding**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnant women should not take more than one dose of 2 tablets. If Potassium iodide G.L. Pharma is taken in late pregnancy, it is recommended to check the thyroid function of the newborn.

Breast-feeding women should not take more than one dose of 2 tablets.

Iodide is excreted into breast milk, but the amount is not enough for the complete protection of the baby. Therefore, iodide tablets have to be given to the baby as well.
(See section 3, “How to take Potassium iodide G.L. Pharma”.)

**Driving and using machines**
Potassium iodide has no influence on the ability to drive or use machines.

**Potassium iodide G.L. Pharma contains lactose**
This medicine contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## 3. How to take Potassium iodide G.L. Pharma

Iodine tablets may only be taken in cases of nuclear accidents and if announced by the respective authority, e.g. via radio or television.
**Do not take the tablets on your own account.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For best possible protection it is necessary to take the tablets as soon as possible (preferably within two hours) after the announcement that radioactive iodine has been released.
However, it is still useful to take the tablets up to 8 hours after the exposure to radioactive iodine.

The tablets can be chewed or swallowed whole. For sucklings, the tablets can be pulverized or dispersed in water, syrup or similar liquids. It may take up to 6 minutes until the tablets are fully dispersed. Make sure that the tablets are fully dispersed before you give them to your child.

The recommended dose is:

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| Adults and children 12 years or older: | 2 tablets |
| Children aged 3 to 12 years: | 1 tablet |
| Children aged 1 month to 3 years: | ½ tablet |
| Newborns and babies younger than 1 month: | ¼ tablet |
| Pregnant women (all ages): | 2 tablets<br>With this dose your unborn child is protected as well. |
| Breast-feeding women (all ages): | 2 tablets |

Newborns, pregnant and breast-feeding women and adults older than 60 years should not take more than one single dose.

Potassium iodide G.L. Pharma 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. 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 iodine thyroid blocking treatment.

The single intake of the above mentioned doses protects against the possible uptake of radioactive iodine.

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

The tablet can be divided into equal doses.

**If you take more Potassium iodide G.L. Pharma than you should**
Taking more of Potassium iodide G.L. Pharma than described above does not increase the protective effect. If you have taken too much of Potassium iodide G.L. Pharma, iodine poisoning may occur with severe side effects such as respiratory and heart problems.
If you have taken too much of Potassium iodide G.L. Pharma, contact your doctor immediately.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Rare (may affect up to 1 in 1 000 people):
- Temporary skin rash.

Not known (frequency cannot be estimated from the available data):
- Hypersensitivity reactions such as swollen salivary glands, headache, wheezing or coughing, and stomach upset
- Iodine-induced autoimmune disorders (Grave's disease, Hashimoto's disease), harmful nodular goitre and iodine-induced temporary thyroid hyperfunction or hypofunction
- Overactive thyroid gland (characterised by weight loss, increased appetite, intolerance to heat and increased sweating), inflammation of the thyroid, enlarged thyroid gland with or without the development of myxoedema (a condition in which there is a thickening of the skin and body tissues, most notably the face)
- Depression, nervousness, impotence, and sleeplessness (after continued administration)
- Sialadenitis (an inflammation of the saliva gland), gastrointestinal disturbances

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system:
IMB Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Potassium iodide G.L. Pharma

Keep this medicine out of the sight and reach of children.

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

Do not use this medicine after the expiry date which is stated on the blister and carton after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Potassium iodide G.L. Pharma contains**

- The active substance is potassium iodide. 1 tablet contains 65 mg potassium iodide, equivalent to 50 mg iodine.
- The other ingredients are maize starch, lactose monohydrate, microcrystalline cellulose (E 460), basic butyl methacrylate copolymer, magnesium stearate (E 572).

**What Potassium iodide G.L. Pharma looks like and contents of the pack**
The tablets are white to white-brown in colour, round, curved and have a cross-shaped pressure-sensitive break line on the inner side and notches on the outer side.

Blister packs containing 2, 4, 6, 10 or 20 tablets

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**
G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach, Austria

**This medicinal product is authorised in the Member States of the EEA under the following names:**

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| The Netherlands: | Kajodan 65 mg tabletten |
| Bulgaria: | калиев йодид G.L. Pharma 65 mg таблетки |
| Cyprus: | ιωδιούχο κάλιο G.L. Pharma 65 mg δισκία |
| Czech Republic: | Jodid draselný G.L. Pharma 65 mg tablety |
| Estonia: | Potassium iodide G.L. Pharma |
| Finland: | Kaliumjodidi G.L. Pharma 65 mg tablettia |
| Ireland: | Potassium iodide G.L. Pharma 65 mg tablets |
| Iceland: | Kalíumjoðíði G.L. Pharma 65 mg töflur |
| Latvia: | Potassium iodide G.L. Pharma 65 mg tabletes |
| Lithuania: | Potassium iodide G.L. Pharma 65 mg tablets |
| Malta: | Potassium iodide G.L. Pharma 65 mg tablets |
| Poland: | Jodek potasu G.L. Pharma |
| Portugal: | Iodeto de potássio G.L. Pharma 65 mg comprimidos |
| Romania: | Iodură de potasiu G.L. Pharma 65 mg comprimate |
| Sweden: | Kaliumjodid G.L. Pharma 65 mg tabletter |
| Slovak Republic: | Jodid draselný G.L. Pharma 65 mg tablety |

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| Slovenia: | Kalijev jodid G.L. Pharma 65 mg tablete |
| United Kingdom: | Potassium iodide 65 mg tablets |

**This leaflet was last revised in .**