**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Kaliumjodide G.L. 65 mg tabletten**
Potassium iodide

**Read all of this leaflet carefully because it contains important information for you.**
This medicine is available without prescription. However, you still need to take Kaliumjodide G.L. 65 mg carefully to get the best results from them.
- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**


## 1. WHAT KALIUMJODIDE G.L. 65 MG 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.

a) b)

*Figure 1. a) Saturation of the thyroid gland with natural iodine from the potassium iodide tablets b) Radioactive iodine cannot be taken up by and accumulate in the thyroid gland and thus the thyroid gland is protected.*

## 2. BEFORE YOU TAKE KALIUMJODIDE G.L. 65 MG

**Do not take Kaliumjodide G.L. 65 mg**

- if you are allergic to one of the ingredients of this medicine. You can find these ingredients in section 6.
- 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).
- if you have an autoimmune disease involving itching and blisters of your skin (dermatitis herpetiformis van Dühring).

**Take special care with Kaliumjodide G.L. 65 mg**

- if you have a malign tumor in your thyroid or if your doctor assumes that you have one. You should not take Kaliumjodide G.L. 65 mg.
- if you have a narrowing of your wind-pipe. The use of Kaliumjodide G.L. 65 mg may worsen this circumstance.

The use of Kaliumjodide G.L. 65 mg may influence the results of thyroid tests.

Ask your doctor for advice if one of the above mentioned circumstances applies to you.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Please remember that this information can also be applicable to medicines which you have taken/used recently.
If you are taking medicines inhibiting the thyroid function, you need to tell your doctor.

**Pregnancy and lactation**

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnant women may take a maximum of 2 tablets. If Kaliumjodide G.L. 65 mg is taken in late pregnancy, it is recommended to check the thyroid function of the newborn.
Breast-feeding women may take a maximum of 1 dose (in this case 2 tablets, see section “How to take Kaliumjodide G.L. 65 mg”).
Iodide is excreted into breast milk, but the amount is not enough for the complete protection of the baby. Therefore, Potassium iodide has to be given to the baby as well.

**Important information about some of the ingredients of Kaliumjodide G.L. 65 mg**

If you think that you are unable to tolerate certain sugars, please consult your doctor before taking this medicine.

## 3. HOW TO TAKE Kaliumjodide G.L. 65 mg?

Always take Kaliumjodide G.L. 65 mg exactly as your doctor has told you. Are you not unsure about proper use? Please contact your doctor or pharmacist.

Iodine tablets may only be taken if announce by the respective authority, e.g. via radio or television.
**Do not take the tablets on your own account.**

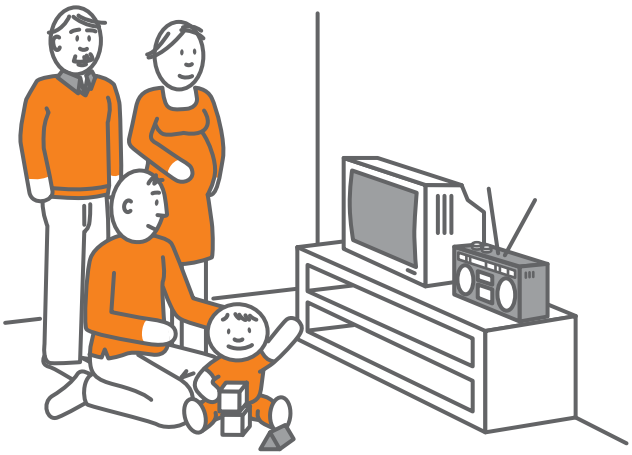
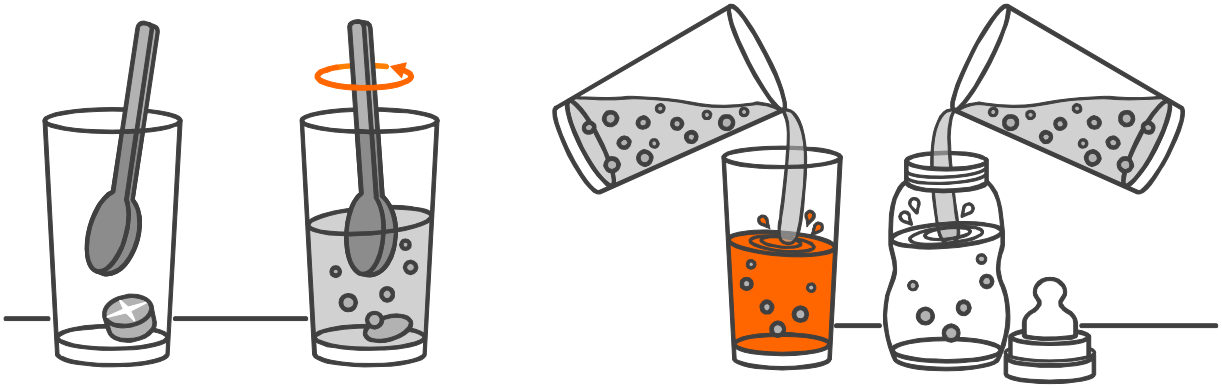


*Figure 2. Watch TV or listen to the radio and wait for recommendations from the government*

For optimal protection it is necessary to take the tablets as soon as possible after the announcement that radioactive iodine has been released.
If the tablets are taken 4 to 6 hours after the exposure to radioactive iodine, protection is approximately 50%. The intake is useless 12 hours after the exposure, because the thyroid has already taken up radioactive iodine.

The tablets can be chewed or swallowed. For sucklings, the tablets can be pulverized or dissolved in water, syrup or similar liquids.

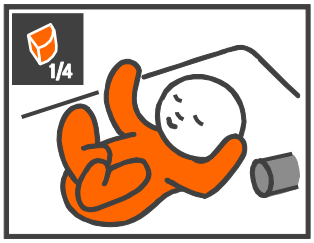


a) b)

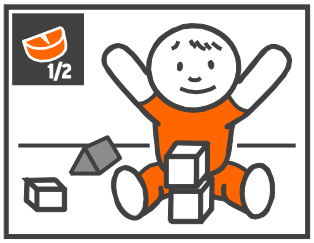
*Figure 3. a) First dissolve the iodine tablet in a small amount of water b) Add this solution to a larger amount of beverage such as water, fruit juice, or (expressed breast) milk*

Adults up to 40 years and children 12 years or older: 2 tablets
Children aged 3 to 12 years: 1 tablet
Children aged 1 month to 3 years: a half tablet
Newborns and babies younger than 1 month: a quarter tablet
Pregnant women (all ages): 2 tablets. With this dose your unborn child is protected as well.

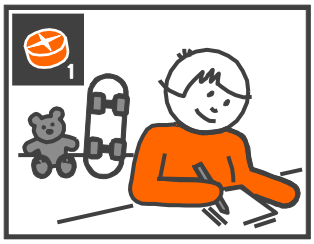
Persons older than 40 years should not take iodine tablets, because at this age there is no increased risk for thyroid cancer caused by exposure to radioactive iodine.



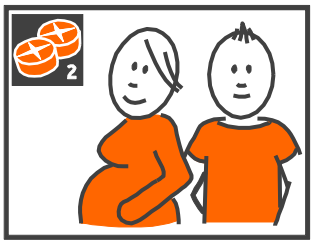

UP TO ONE MONTH:
A SINGLE DOSE OF A QUATER OF A TABLET




ONE MONTH TO 3 YEARS:
A SINGLE DOSE OF A HALF TABLET

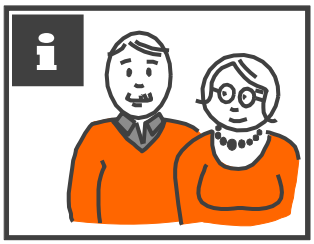



FROM 3 TO 12 YEARS:
A SINGLE DOSE OF A TABLET




FROM 13 TO 40 YEARY:
A SINGLE DOSE OF 2 TABLETS

PREGNANT WOMEN AND BREASTFEEDING WOMEN (regardless of age):
A SINGLE DOSE OF 2 TABLETS



FROM 40 YEARS:
ASK YOUR PREVENTIVE PHYSICIAN OR SPECIALIST

*Figure 3. Recommended amount of iodine tablets per age group*

The single intake of the above mentioned doses guarantee complete protection against the possible uptake of radioactive iodine if inhaled when the radioactive cloud passes by.

If the release of radioactive iodine continues and thus also the exposure by inhalation, the above mentioned doses should be given on a daily basis as long as the release of radioactive iodine continues.

Breast-feeding and pregnant women as well as newborn children must not be given more than a single dose. Children developing skin reactions after the first intake must not receive further doses as well.

**If you take more Kaliumjodide G.L. 65 mg than you should**
Persons who have previously been treated for thyreotoxicosis or thyroiditis and who have taken high iodine doses are at risk for permanent lack of thyroid hormones (hypothyroidism).
Persons treated with thyroid hormones do not have an increased risk for side effects.
If you have taken too much of Kaliumjodide G.L. 65 mg, contact your doctor immediately.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Kaliumjodide G.L. 65 mg can cause side effects, although not everybody gets them.

Rare::
Temporary skin rash.

Do you suffer from a side-effect? Or do you have any other side-effect? Please contact your doctor or pharmacist..

## 5. HOW TO STORE Kaliumjodide G.L. 65 mg ?

Keep out of the reach and sight of children.

Do not store above 30°C.
Store in the original package in order to protect from light.

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.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

**What Kaliumjodide G.L. 65 mg 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 Kaliumjodide G.L. 65 mg 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.
The tablet can be divided into equal halves and quarters.

Blister packs containing 6, 10 or 20 tablets

**Marketing authorisation holder and manufacturer**

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

**Marketing authorisation number**

RVG 106104

**This leaflet was last revised in September 2017.**