**PACKAGE LEAFLET**

**Package leaflet: Information for the patient**

**Kaliumjodid SERB 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 use this medicine exactly as described in this leaflet or as your doctor, or pharmacist has told you.

[For medicines available only on prescription]
< - Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.>

[For medicines available without prescription]
< - 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 Kaliumjodid SERB is and what it is used for
2. What you need to know before you take Kaliumjodid SERB
3. How to take Kaliumjodid SERB
4. Possible side effects
5. How to store Kaliumjodid SERB
6. Contents of the pack and other information


## 1. What Kaliumjodid SERB is and what it is used for

This medicinal product should only be taken after explicit instructions of the competent authorities in accordance with official national recommendations.

Kaliumjodid SERB tablets are intended for use by the population in case radioactive iodine would be released into the air in the event of a nuclear accident. The tablets are used to prevent the uptake of radioactive iodine by the thyroid gland.
In case of a nuclear accident, a message regarding the use of iodine tablets will be communicated via the media (radio, television, internet) by the national competent authorities.

The uptake of radioactive iodine in the thyroid gland can be blocked by rapid administration of a high dose of potassium iodide. The thyroid gland has then already absorbed enough iodine and no more radioactive iodine is taken up during 24h.

## 2. What you need to know before you take Kaliumjodid SERB

**Do not take Kaliumjodid SERB**
- If you are allergic to potassium iodide or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from dermatitis herpetiformis (also called Duhring-Brocq disease), a rare skin disease

- If you suffer from hypocomplementaemic urticarial vasculitis (also called Mac Duffie syndrome), a rare disease causing inflammation of the blood vessels

**Warnings and precautions**
This medicinal product should be taken immediately after explicit instructions of the national competent authorities.
The late intake of potassium iodide tablets (24 hours after exposure) may be harmful as it would prolong the presence of radioactive iodine that has accumulated in the thyroid.

Children, adolescents, pregnant and breastfeeding women as well as those living in iodine-poor areas are most likely to benefit from treatment with iodine tablets after exposure to radioactive iodine. Adults over 40 years old are less likely to benefit from treatment with iodine tablets after exposure to radioactive iodine.
If the supply of Kaliumjodid SERB is limited, priority should be given to children and young adults as well as persons at risk of exposure to high doses of radioactive iodine (i.e. workers involved in rescue or cleaning operations) regardless of their age.

The tablets do not protect against any other type of radiation from radioactive substances.

**Talk to your doctor or pharmacist before taking Kaliumjodid SERB if you :**
- are being treated for a thyroid problem.
- are being treated for thyroid cancer or if your doctor suspects that you have one.
- have difficulties to breath or swallow. The use of Kaliumjodid SERB may worsen this condition due to the enlargement of the thyroid gland, i.e goitre (see section 4 Possible side effects).

**Children**
- The risk of thyroid gland cancer after exposure to radioactive iodine is greater in younger individuals. As their thyroid gland is still growing, newborns (birth to 1 month of age) and children are more susceptible to the dangerous effects of radioactive iodide than adults and should be treated with potassium iodide in priority.
- Repeated administration of potassium iodide should be avoided in newborns to minimize the risk of underactive thyroid.
- For newborns, surveillance of the thyroid by a doctor is recommended to ensure prompt treatment against hypothyroidism (a condition where the thyroid doesn‘t produce enough hormones) which may occasionally occur following potassium iodide administration (see section 4 Possible side effects). Hypothyroidism in newborns may affect brain development..

**Other medicines and Kaliumjodid SERB**
The risk of interactions is low when the medicinal product is used in accordance with the recommended posology.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription.
In particular, you may seek medical attention when using the following medicines while taking Kaliumjodid SERB:
- Angiotensin Converting Enzyme (ACE) inhibitors, a group of medicines that work by helping to widen your blood vessels, which then make it easier for your heart to pump blood through them (medicines of the same type as captopril or enalapril),
- Potassium sparing diuretics (water tablets that decrease the amount of potassium lost in the urine) such as amiloride, triamterene or aldosterone antagonists,
- Lithium, used in mental illnesses,
- Medicines that treat an over-active thyroid gland (disease called “hyperthyroidism”) (medicines of the same type as carbimazole, methimazole, and propylthiouracil),
- Medicines already containing iodine (i.e amiodarone used to correct an irregular heartbeat).

The use of Kaliumjodid SERB may influence radioiodine therapy and the results of thyroid tests.

**Kaliumjodid SERB with food and drink**

Food in the stomach may delay the absorption . Therefore, it is preferable to take tablet away from food intake.

**Pregnancy and breast-feeding**
Pregnant women should take potassium iodide for their own protection and for that of the unborn child.
Pregnant and breast-feeding women should not take repeat doses.
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.

**Kaliumjodid SERB contains lactose**
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 Kaliumjodid SERB

This medicinal product should only be taken after explicit instructions of the national competent authorities. Do not take this medicinal product on your own judgement.

[For medicines available only on prescription]
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

[For medicines available without prescription]
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.

The optimal period of administration of potassium iodide is less than 24 hours prior to, and up to 2 hours after the expected onset of exposure. It would still be reasonable to administer potassium iodide up to 8 hours after the estimated onset of exposure.

A single dose of potassium iodide results in an almost complete saturation of the thyroid, blocking the uptake of radioactive iodine by the thyroid gland for the next 24h.

Do not use this medicine later than 24 hours following exposure to radiation (see section 2 Warnings and precautions).

There are no available data to suggests that a dosage adjustment is required in older adults (over 60 years) and in patients with renal or liver problem. There is a risk of accumulation of drug in these populations so potassium iodide should not be given for a longer period of time.

The recommended dose is defined according to the age of the patient.

| | Potassium iodide dose | Number of tablets to be taken |
|---|---|---|
| Adults including pregnant and breastfeeding women | 130 mg | 2 |

**Use in children and adolescents**

| | Potassium iodide dose | Number of tablets to be taken |
|---|---|---|
| Adolescents (above 12 years old) | 130 mg | 2 |
| Children (from 3 to 12 years old) | 65 mg | 1 |
| Infants | 32 mg | 1/2 |

| | | |
|---|---|---|
| (from 1 month to 3 years old) | | |
| Newborns (<1 month) | 16 mg | 1/4 |

*Repeated doses in case of prolonged exposure*
In case of prolonged exposure, additional doses may be necessary following explicit instructions of the national competent authorities.
Newborns (<1 month), pregnant and breastfeeding women and older adults (over 60 years) should not receive repeated doses of potassium iodide.

*Method of administration*
The tablet can be divided into two or four equal doses to facilitate the dosage for children.
The tablet can be chewed, swallowed, or crushed and mixed with fruit juice, jam, milk or similar substance.
In case of dissolution, the solution must be taken immediately.
Food in the stomach may delay the absorption. Therefore, it is preferable to take tablet away from food intake.

**If you take more Kaliumjodid SERB than you should**
Taking higher doses of potassium iodide does not increase the protective effect. If you (or someone else) have taken too much potassium iodide, contact a doctor, hospital or casualty department for advice.

Symptoms
- Bitter taste in the mouth, you may have more saliva than usual, burning sensation in the mouth and pain in the mouth;
- Nasal allergy symptoms, swelling and inflammation of the throat and salivary glands. Eyes may be irritated and swollen and there may be more tears than usual.
- An enlargement or swelling of the lungs, difficulty breathing, and breathing distress caused by narrowing of the airways may develop.
- Skin reactions include mild pimple-like eruptions or, more rarely, severe eruptions

Management of overdose
In case of drug overdose, it is advised to contact the anti-poison center nearby.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

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

The following side effects, presented by frequency, have been described:
Common (may affect up to 1 in 10 people):
- Vomiting
- Diarrhoea
- Stomach pain
- Skin rash

Not known (frequency cannot be estimated from the available data):
- Allergic reactions*
- Metallic taste
- Thirst
- Abdominal pain
- Bloody diarrhoea

- Signs of overactive thyroid: acceleration of heart rate, heart palpitations, fatigue, abundant sweating, change in appetite, acceleration of transit with diarrhoea, intolerance to heat, menstrual disorders, nervousness, anxiety, irritability, emotional instability, sleeping troubles.
- Signs of underactive thyroid: slow heart rate, fatigue, chilliness, moderate weight gain, constipation, shortness of breath, muscle stiffness, cramps, menstrual disorders, dry skin, brittle nails and hair, intellectual slowness, hoarse voice, irritability, depression.
- Enlargement of the thyroid (Goitre)

*Allergic reactions are exceptional. Those may include difficulty in breathing (bronchospasm), hives (urticaria), swelling under the skin, particularly around the eyes and lips (angioedema), cutaneous bleeding or purplish spots (purpura) on the skin, fever, joint pain, swollen lymph glands (lymphadenopathy), and increase of the number of a certain type of white blood cells (eosinophilia).

*Additional side effects in children*
A temporary increase in thyroid hormone levels in the blood has been observed in newborns in the first few days of their life.

**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 listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Kaliumjodid SERB

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

This medicine does not require any special temperature storage conditions.
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 box/blister after EXP. The expiry date refers to the last day of that month.

The tablets may become slightly yellow during storage. This discolouration will not affect the preventive effect.

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 to protect the environment.

## 6. Contents of the pack and other information

**What Kaliumjodid SERB contains**
- The active substance is potassium iodide 65 mg (corresponding to 50 mg iodine).
- The other ingredients are lactose, microcrystalline cellulose, magnesium stearate.

**What Kaliumjodid SERB looks like and contents of the pack**
Kaliumjodid SERB 65 mg tablets are white to off-white, flat bevelled, with a cross line on one side, diameter 9 mm.
The tablets are packed in blisters in boxes of 10 and 20 tablets.

**Marketing Authorisation Holder and Manufacturer**

<To be completed nationally>

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**
<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

**This leaflet was last revised in** <To be completed nationally>
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