

Potassium Iodate 85mg Tablets

Potassium Iodate

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 doctor or 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 lodate 85mg Tablets are and what they are used for
- 2. What you need to know before you take Potassium Iodate 85mg Tablets
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1. What Potassium lodate 85mg Tablets are and what they are used for

Potassium lodate is a thyroid blocking agent, and is used for example after a nuclear accident.

Potassium lodate tablets are used at the time of a nuclear emergency; the tablets stop the thyroid gland (situated in your neck) taking up radioactive iodine, which may be released into the environment following a nuclear accident.

Radioactive lodine is harmful and especially dangerous to babies and children. Ask your doctor, pharmacist or emergency coordinator if you need additional information especially concerning the correct use of this product.

2. What you need to know before you take Potassium lodate 85mg Tablets Do not take Potassium lodate if:

• you are allergic to potassium iodate, iodine or any of the other ingredients of this medicine (listed in section 6).

Keep in mind that if you are allergic to any iodine product, then you will also be allergic to Radioactive Iodine. This therefore means you have an additional risk that should be discussed with your doctor.

- suffer from dermatitis herpetiformis (an itchy skin disease which is associated with gluten sensitivity).
- you suffer from hypocomplementaemic vasculitis (a disease causing inflammation of the blood vessels with pain depending on which area is involved).
- you have severe problems with your kidneys, i.e. kidney failure.

Make sure your doctor knows if you suffer from any of the above.

Warnings and precautions

Talk to your doctor before taking Potassium Iodate 85mg Tablets:

- if you have ever been treated for an overactive thyroid gland.
- if you have, or you are being treated for problems with your kidneys or adrenal glands.
- if you are suffering from dehydration or cramp due to extreme heat.

If the answer to any of these questions is YES, do not take Potassium lodate before talking to a doctor or pharmacist.

Other medicines and Potassium Iodate 85mg Tablets

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 not be able to use the following medicines whilst you are taking Potassium lodate 85mg Tablets:

- Some drugs used to treat heart problems or high blood pressure, such as quinidine or ACE inhibitors (eg. captopril or enalapril).
- Diuretics ("water tablets") which may affect the level of potassium in the blood such as amiloride or triamterene.
- Other drugs that may affect the thyroid, including lithium (used in the treatment of mania, bipolar disorder, and recurrent depression) and amiodarone (used in the treatment of abnormal heart rhythms).

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 for advice before taking this medicine.

Pregnancy:

Potassium lodate may be taken during pregnancy however the number of doses should be kept to a minimum and repeat dosing should be avoided. You must also get medical advice since Potassium lodate may affect the thyroid of your child and tests from your doctor can establish and correct this.

You should not take this medicine if you are pregnant and have been diagnosed by your doctor as having an overactive thyroid gland (a condition called hyperthyroidism).

Breast-feeding:

You should continue to breast-feed if you are taking this medicine. Repeat dosing of Potassium lodate should be avoided if you are breast-feeding.

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

Driving and using machines

Potassium lodate should not affect your ability to drive or use machinery.

3. How to take Potassium Iodate 85mg Tablets

This medicine should be taken after a nuclear accident. Emergency co-ordinators will advise you on the correct actions to take.

The tablets should be taken as a single dose as soon as you are advised to do so; delay may result in reduced effectiveness. The usual recommended dose is as follows:

Adults (including the elderly and children over 12 years):

2 tablets
100mg
Children aged 3 – 12 years:
1 tablet
50mg
Children aged 1 month – 3 years:
½ tablet
25mg
Newborn Babies aged up to 1 month:
½ tablet
12.5mg
(or 12.5mg iodine equivalent as standard solution)

For babies the dose may be crushed and taken mixed with milk or juice. For children the dose may be crushed and taken mixed with e.g. jam, honey or yoghurt.

For newborn babies living at home, a dosage of ¼ tablet is acceptable. This can be crushed and mixed with milk or water. For newborn babies still in hospital, an exact dosage of 12.5mg iodine equivalent can be given as a standard solution freshly prepared from Potassium Iodide crystals (kept in maternity wards).

In cases of prolonged exposure repeat dosing may be necessary, however in pregnant or breastfeeding women and newborn babies (aged up to 1 month) repeat dosing should be avoided. After taking Potassium lodate, babies up to a month old should be taken to see their doctor to have their thyroid function assessed.

If you take more Potassium lodate 85mg Tablets than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has accidentally swallowed any of the tablets, contact your nearest hospital casualty department or a doctor immediately.

An overdose can cause the following:

- headache
- pain and swelling in and around the throat
- fever
- diarrhoea and vomiting
- fluid on the lungs causing breathlessness
- vision problems
- bleeding in the stomach/ intestine (causing vomiting of blood, bloody bowel movements, or black stools)
- blood disorders including intravascular haemolysis (breakdown of red blood cells, symptoms may include dark coloured urine), disseminated intravascular coagulation (problems with blood clotting and/ or bleeding), and methaemoglobinaemia (commonly causing blue or purple colouration of the skin).

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

4. Possible side effects

Like all medicines, Potassium Iodate 85mg Tablets can cause side-effects, although not everybody gets them. In fact, it is taken by the majority of patients without any problems.

The following side effects have been reported but how often they occur is unknown:

- Allergic reactions such as a rash, swollen salivary glands which are around the side of the face and neck, headache, wheezing or coughing.
- Stomach upsets, feeling sick, disturbances of taste including a metallic taste in the mouth.
- Interference with the function of the thyroid gland which can result in either over or under activity. An over active thyroid may cause weight loss, increased appetite and increased pulse rate. An under active thyroid may cause lethargy (loss of energy), intolerance to cold, constipation and puffiness of the face.
- An enlargement or swelling of the thyroid gland in the neck. This may be caused by a problem with your immune system (known as Grave's Disease or Hashimoto's Disease), and may also cause the symptoms of an over active thyroid gland described above.
- · Continued use of this medicine may lead to depression, nervousness, difficulty sleeping and difficulty with erections in men.

In the event of a nuclear emergency, there are other protective actions you can take against radiation damage. Emergency assistance should be sought in order to avoid further dangerous contamination.

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 internet at www.mhra.gov.uk/yellowcard or call Freephone 0808 100 3352. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Potassium Iodate 85mg Tablets

Keep this medicine out of the sight and reach of children - preferably in a locked cupboard or medicine cabinet.

Do not use this medicine after the expiry date shown on the outside packaging. The expiry date refers to the last day of that month.

These tablets should be stored in a dry place below 25°C in the package or container supplied. Do not transfer them to another container.

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

6. Contents of the pack and other information

What Potassium Iodate 85mg Tablets contain

The active substance is Potassium Iodate. Each tablet contains 85mg of Potassium Iodate which is equivalent to 50mg of iodine. The other ingredients are calcium hydrogen phosphate, croscarmellose sodium, microcrystalline cellulose and magnesium stearate.

What Potassium lodate 85mg Tablets look like and contents of the pack

Potassium lodate 85mg Tablets are off-white in colour and round, with a star shaped double break line, engraved 2202.

The product is available in blister packs of 6, 10 and 100 tablets, or in pots of 50, 100, 500 or 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation holder

Alliance Pharmaceuticals Limited, Avonbridge House, Bath Road, Chippenham, Wiltshire, SN15 2BB, UK.

Manufacturer

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