LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Kaliumjodid SERB
(iodine, potassium iodide)

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Summary Public Assessment Report

Kaliumjodid SERB
potassium iodide

Tablet, 65 mg

This is a summary of the public assessment report (PAR) for Kaliumjodid SERB. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Kaliumjodid SERB and what is it used for?

The product is a medicine with 'well-established use'. This means that the medicinal use of the active substance of the product is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

This medicinal product should only be taken when there is a risk of exposure to nuclear radiation and after explicit instructions of the competent authorities.

Kaliumjodid SERB tablets are intended for use by the population near a nuclear reactor in case radioactive iodine would be released into the air in the event of a nuclear power accident. The tablets are used as a prophylactic treatment against the effects on the thyroid gland.
In case of a nuclear reactor accident a message regarding the use of iodine tablets is sent on the media (radio, television, internet) by the authorities.

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

How does Kaliumjodid SERB work?

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.

How is Kaliumjodid SERB used?

The pharmaceutical form is tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can be obtained without a prescription in Sweden.

What benefits of Kaliumjodid SERB have been shown in studies?

As potassium iodide is a well-known substance, and its use (see section "What is Kaliumjodid SERB and what is it used for?") is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of potassium iodide in the treatment of the above-mentioned indication.

What are the possible side effects from Kaliumjodid SERB?

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Kaliumjodid SERB approved?

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Kaliumjodid SERB?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Kaliumjodid SERB

The full PAR for Kaliumjodid SERB can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Kaliumjodid SERB, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2022-11-02.