

Package Leaflet: Information for the user

Radiogardase®-Cs 500 mg hard capsules



Active substance: Ferric hexacyanoferrate(II)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you

- 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.

What is in this leaflet

1. What Radiogardase-Cs is and what it is used for
2. What you need to know before you take Radiogardase-Cs
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1. What Radiogardase-Cs is and what it is used for

Radiogardase-Cs contains ferric hexacyanoferrate(II) [Prussian blue insoluble] and is used as an antidote at contamination of radioactive cesium.

Radiogardase-Cs is indicated for excretion (decorporation) or avoidance of the uptake (resorption) of radioactive cesium (e.g. ^{134}Cs or ^{137}Cs).

2. What you need to know before you take Radiogardase-Cs

Do not take Radiogardase-Cs,

if you are allergic to ferric hexacyanoferrate(II) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Radiogardase-Cs.

Other medicines and Radiogardase-Cs

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take / use any other medicines.

- Radiogardase-Cs may bind to other orally administered drugs and essential nutrients. Therefore the drug levels and the clinical response to the therapy should be monitored.
- Radiogardase-Cs may inhibit the absorption of tetracyclines.
- Radiogardase-Cs may bind electrolytes present in the gastrointestinal tract (e.g. potassium), which can result in lowered potassium levels in serum (asymptomatic hypokalemia). Therefore serum electrolytes should be closely monitored during therapy. Caution should be exercised when treating patients with pre-existing cardiac arrhythmias or electrolyte imbalances.

- The co-administration of other radioeliminators does not affect the efficacy of Radiogardase-Cs for radioactive cesium.

Radiogardase-Cs with food, drink and alcohol

No effects are known so far. See also section 3.

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.

There are no concerns about the use of Radiogardase-Cs during pregnancy and lactation. Since Radiogardase-Cs is practically not absorbed from the gastrointestinal tract, it does not pass the placental barrier and is not excreted into breast milk. However, radioactive cesium is transmitted as well to the unborn child as into breast milk. Therefore the risk of radioactive cesium is expected to be greater than the risk of a treatment with Radiogardase-Cs.

Radioactively contaminated mothers should not breast-feed in general.

Driving and using machines

No effects are known so far.

Radiogardase-Cs contains sodium.

This drug contains less than 1 mmol (23 mg) of sodium per hard capsule, which means it is virtually "sodium-free".

3. How to take Radiogardase®-Cs

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

Posology

The dosage depends on the severity of the intoxication with radioactive cesium.

The recommended dose for adults, children and adolescents is:

- 6 to 40 hard capsules of Radiogardase-Cs [3 to 20 g ferric hexacyanoferrate(II)] orally each day. The daily dose should be distributed evenly over the 24-hour period (e.g. 3 x 6 hard capsules daily) in order to optimally interrupt the enterohepatic circulation of the radioactive cesium.
- In cases of acute intoxication, where the radioactive cesium is still present in the stomach or upper parts of the intestinal tract, an initial dose of at least 6 hard capsules [3 g ferric hexacyanoferrate(II)] should be given all at once.

Method of administration

For oral use.

Please take the hard capsules with sufficient liquid (preferably a glass of drinking water).

If you cannot swallow the hard capsule, the capsules may be opened and the content may be taken mixed with food. Ferric hexacyanoferrate(II) (Prussian blue insoluble) may also be drunk dispersed in fluid (e.g. in warm water). This may result in blue discoloration of the mouth and teeth.

If an oral use is not possible, the contents of the hard capsules can be suspended in water or a mannitol solution and administered by stomach or duodenal intubation.

The hard capsules should be taken with meals, since food stimulates bile secretion and the enterohepatic circulation (stimulation of cesium excretion).

Duration of treatment

Treatment with Radiogardase-Cs should be initiated as soon as possible. If Radiogardase-Cs is not available immediately, treatment is still effective and reasonable even after time has elapsed since exposure.

Treatment should continue for a minimum of 30 days and depends on the level of contamination and the judgement of the attending physician. Regular (weekly) checks of radioactivity in stool and urine are important, because the duration of the therapy depends on the detection of radiocesium in stool.

The long biological half-life of radiocesium must be considered. When the internal radioactivity of cesium is substantially decreased the dosage of Radiogardase-Cs may be decreased to 2 to 4 hard capsules daily [1 to 2 g ferric hexacyanoferrate(II)] to improve gastrointestinal tolerance.

If you take more Radiogardase-Cs than you should

Overdosing with Radiogardase-Cs is not known. Symptoms of overdose may be obstipation, obstruction, or severe decrease in electrolytes.

If you have accidentally taken twice your prescribed dose, this does not have any effects on the further intake, i.e. you take Radiogardase-Cs after that as usual.

If you forget to take Radiogardase-Cs

The medication should be continued as usual. Do not take a double dose to make up for a forgotten dose. However, please take into account that Radiogardase-Cs only can work safely and sufficiently if it is taken regularly.

If you stop taking Radiogardase-Cs

If the treatment is interrupted or ended prematurely, radiocesium that has not yet been excreted remains in the body and can lead to radiation damage. Please consult your doctor about this.

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 intake of Radiogardase-Cs can cause constipation. This may be treated with a high fiber diet or fiber based laxatives.
- High-dose therapy (20 g ferric hexacyanoferrate(II) per day) can cause non-specific gastrointestinal complaints.

Note: Dark coloration of the feces is harmless; it is due to the color of the active ingredient ferric hexacyanoferrate(II) [Prussian blue insoluble].

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 Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn, Website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Radiogardase®-Cs

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

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

Do not store above 25 °C.

Do not throw away any medicines via wastewater (e.g., via toilet or washbasin). Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment. You can find further information at www.bfarm.de/arzneimittelentsorgung.


6. Contents of the pack and other information

What Radiogardase-Cs contains

- The active substance is ferric hexacyanoferrate(II).

1 hard capsule contains 0.5 g ferric hexacyanoferrate(II)
(68 % $\text{Fe}_4[\text{Fe}(\text{CN})_6]_3$) (Prussian blue insoluble).
- The other ingredients are: gelatin, indigo carmine (E132), sodium dodecyl sulfate, purified water.

What Radiogardase-Cs looks like and contents of the pack

Radiogardase-Cs is available in a white plastic bottle with 36 blue hard capsules with the light blue inscriptions PB and .

Instruction for opening the bottle



Open the bottle as shown in the picture:

- Step 1: Press firmly on the closure.
- Step 2: Twist the closure while pressing.
- Step 3: Remove seal from plastic container before first use.

Further notes

Please note that the content of the hard capsules has a strong coloration effect (Prussian blue insoluble).

Although Radiogardase-Cs increases the excretion of radioactive cesium, it does not treat the complications of the radiation exposure (bone marrow suppression). Supportive treatment can be necessary in patients with high contamination.

Radiocesium is excreted with stool and urine. Contamination of other people should be avoided by special safety measures.

Marketing authorization holder and Manufacturer

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