

Prussian blue insoluble Capsules 340mg Pru-Decorp

Composition:

Each capsule contains:
Prussian blue insoluble 340 mg
Approved colour used in capsule shells.

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 Pru-Decorp is and what it is used for
2. What you need to know before you take Pru-Decorp
3. How to take Pru-Decorp
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1. WHAT Pru-Decorp IS AND WHAT IT IS USED FOR

Pru-Decorp contains ferric hexacyanoferrate [Prussian blue insoluble] and is used as an antidote at contamination of radioactive cesium. Pru-Decorp is indicated for excretion (decorporation) or avoidance of the uptake (resorption) of radioactive cesium (e.g. 134 Cs or 137Cs).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE Pru-Decorp

Do not take Pru-Decorp, if you are allergic to ferric hexacyanoferrate or any of the other ingredients of this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Pru-Decorp.

Other medicines and Pru-Decorp

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

- Pru-Decorp may bind to other orally administered drugs and essential nutrition. Therefore the drug levels and the clinical response to the therapy should be monitored.

- Pru-Decorp may bind electrolytes found 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.

Pru-Decorp with food, drink and alcohol No consequences are known to this day. 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 reservations against use during pregnancy and breast-feeding.

Since Pru-Decorp 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 Pru-Decorp. Radioactively contaminated mothers should not breast-feed in general.

Driving and using machines

No effect are known so far

3. HOW TO TAKE Pru-Decorp Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dosage depends on the severity of the intoxication with radioactive cesium. The recommended dose for adults, children and adolescents is:

- the recommended dose of Prussian blue insoluble is 3-10 gm per day. The daily dose should be distributed evenly over the 24-hour period in order to optimally interrupt the enterohepatic circulation of the radioactive cesium.

• Route and method of administration

Please take the capsules with sufficient liquid (primarily a glass of drinking water). In patients who cannot tolerate swallowing the capsules, the capsules may be opened and the ingredient may be taken mixed with food. Ferric hexacyanoferrate (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 oral application is not possible, the contents of the capsules can be suspended in water or a mannitol solution and administered by stomach or duodenal intubation. The capsules should be taken with food, since food stimulates bile secretion and the entero hepatic circulation (stimulation of cesium excretion).

Duration of treatment

Treatment with Pru-Decorp should be initiated as soon as possible, If Pru-Decorp 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 judgment of the attending physician.

If you take more Pru-Decorp than you should

Overdosing with Pru-Decorp is not known. Symptoms of overdose may be constipation, 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 Pru-Decorp after that as usual.

If you forget to take Pru-Decorp

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 Pru-Decorp only can work safely and sufficiently if it is taken regularly

If you stop taking Pru-Decorp

At an interruption of the medical treatment please contact your doctor. 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 Pru-Decorp can cause constipation. This may be treated with a high fiber diet or fiber based laxatives. In high dosage (more than 10 g ferric hexacyanoferrate daily) undefined gastric distress may occur.

Note: Dark coloration of the feces is harmless; it is due to the color of the active ingredient ferric hexacyanoferrate [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.

5. HOW TO STORE Pru-Decorp

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. 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 Presentation:

What Pru-Decorp looks like and contents of the pack

Pru-Decorp is available in a white plastic bottle (HDPE) with 36 deep blue capsules.

Instruction for opening the bottle

- 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 references

Please note that the content of the capsules has a strong coloration effect (Prussian blue insoluble). Although Pru-Decorp 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. Radioactive cesium is excreted in the urine and feces. Appropriate safety measures should be taken to avoid contamination of other persons.



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