

## **Antidotum Thallii-Heyl®**

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 Antidotum Thallii-Heyl® is and what it is used for
2. What you need to know before you take Antidotum Thallii-Heyl®
3. How to take Antidotum Thallii-Heyl®
4. Possible side effects
5. How to store Antidotum Thallii-Heyl®
6. Contents of the pack and other information

## **1. WHAT ANTIDOTUM THALLII-HEYL® IS AND WHAT IT IS USED FOR**

Antidotum Thallii-Heyl contains ferric hexacyanoferrate(II) [Prussian blue insoluble] and is used as an antidote at intoxication.

Antidotum Thallii-Heyl is indicated for treatment of thallium poisoning.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ANTIDOTUM THALLII-HEYL®**

### **Do not take Antidotum Thallii-Heyl**

- 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 Antidotum Thallii-Heyl.

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

In cases of acute thallium intoxication supportive treatment such as forced vomiting, gastric lavage or hemodialysis can be necessary.

In cases of poisoning with radioactive thallium it is excreted in the urine and faeces. Appropriate safety measures should be taken to avoid contamination of other persons.

### **Other medicines and Antidotum Thallii-Heyl**

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

- Antidotum Thallii-Heyl may bind to other orally administered drugs and essential nutrients. Therefore the drug levels and the clinical response to the therapy should be monitored.
- Antidotum Thallii-Heyl may inhibit the absorption of tetracyclines.
- Antidotum Thallii-Heyl 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.

- In cases of poisoning with radioactive thallium the co-administration of other drugs for treatment of contamination with radioactive substances does not affect the efficacy of Antidotum Thallii-Heyl for thallium.

#### **Antidotum Thallii-Heyl 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 of Antidotum Thallii-Heyl during pregnancy and breast-feeding.

Since Antidotum Thallii-Heyl is practically not absorbed from the gastrointestinal tract, it does not pass the placental barrier and is not excreted into breast milk. However, thallium is transmitted both to the fetus and into breast milk. Therefore the risk of thallium is expected to be greater than the risk of a treatment with Antidotum Thallii-Heyl.

Mothers contaminated with thallium should not breast-feed in general.

#### **Driving and using machines**

No consequences are known to this day.

### **3. HOW TO TAKE ANTIDOTUM THALLII-HEYL®**

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 thallium.

The recommended dose is for adults, children over 2 years and adolescents:

- if absorption of thallium has already taken place, and for chronic thallium intoxication 6 to 40 hard capsules of Antidotum Thallii-Heyl [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 thallium;
- in cases of acute intoxication, where the thallium 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)] in one dose.

#### **Route and method of administration**

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

Patients who cannot swallow the capsules may open them 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 oral application is not possible, the content 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 food, since food stimulates bile secretion and the enterohepatic circulation (stimulation of thallium excretion).

#### **Duration of administration**

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

Treatment depends on the excretion of thallium in the faeces.

#### **If you take more Antidotum Thallii-Heyl than you should**

Overdosing with Antidotum Thallii-Heyl 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 Antidotum Thallii-Heyl after that as usual.

#### **If you forget to take Antidotum Thallii-Heyl**

Do not take a double dose to make up for a forgotten dose. However, please take into account that Antidotum Thallii-Heyl only can work safely and sufficiently if it is taken regularly.

#### **If you stop taking Antidotum Thallii-Heyl**

At an interruption or shorten of the medical treatment not excreted thallium still remains in the body and can lead to intoxication. Please contact your doctor to 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 Antidotum Thallii-Heyl can cause constipation. This may be treated with a high fibre diet or fibre-based laxatives.

In high dosage (20 g ferric hexacyanoferrate(II) daily) undefined gastric distress may occur.

Note: Dark coloration of the faeces is harmless; it is due to the colour 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 to Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn, Website: [www.bfarm.de](http://www.bfarm.de). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE ANTIDOTUM THALLII-HEYL®**

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 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 Antidotum Thallii-Heyl contains**

The active substance is ferric hexacyanoferrate(II).

1 hard capsule contains 500 mg ferric hexacyanoferrate(II)  
(68 %  $\text{Fe}_4[\text{Fe}(\text{CN})_6]_3$ ) (Prussian blue insoluble).

The other ingredients are: microcrystalline cellulose, gelatin, indigo carmine (E132), sodium dodecyl sulfate, water for injection.

**What Antidotum Thallii-Heyl looks like and content of the pack**

Antidotum Thallii-Heyl is available in a jar with 30 blue hard capsules.

**Marketing authorization holder**

**Heyl** Chem.-pharm. Fabrik

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Haupt Pharma Berlin GmbH

Moosrosenstraße 7

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This drug is approved under the following names in the member states of the European Economic Area (EEA):

Federal Republic of Germany: Antidotum Thallii-Heyl®

**This leaflet was revised last in March 2015.**