

Package leaflet: Information for the patient

Zink-Trinatrium-pentetat (Zn-DTPA) 1 055 mg / 5 ml solution for injection



Active substance: Trisodium zinc pentetate

Read all of this leaflet carefully before administration of this medicine is started 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. 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 Zink-Trinatrium-pentetat (Zn-DTPA) is and what it is used for
2. What you need to know before you use Zink-Trinatrium-pentetat (Zn-DTPA)
3. How to use Zink-Trinatrium-pentetat (Zn-DTPA)
4. Possible side effects
5. How to store Zink-Trinatrium-pentetat (Zn-DTPA)
6. Contents of the pack and other information

1. What Zink-Trinatrium-pentetat (Zn-DTPA) is and what it is used for

Zink-Trinatrium-pentetat (Zn-DTPA) contains Trisodium zinc pentetate and serves as an antidote at radionuclide poisoning.

Zink-Trinatrium-pentetat (Zn-DTPA) is used for long-term treatment of poisoning with radioactive metals (americium, plutonium, curium, californium, berkelium).

2. What you need to know before you use Zink-Trinatrium-pentetat (Zn-DTPA)

Do not use Zink-Trinatrium-pentetat (Zn-DTPA),

- if you are allergic to DTPA or its salts or any of the other ingredients of this medicine (listed in section 6).
- at hyperzinaemia or
- at an oral uptake of radionuclides as long as the nuclide is still in the gastro-intestinal tract since the complexed radionuclide is better absorbed than the uncomplexed one.

Zink-Trinatrium-pentetat (Zn-DTPA) should not be used at poisoning with uranium, neptunium or cadmium.

Warnings and precautions

Talk to your doctor or pharmacist before Zn-DTPA is administered.

The daily dose may not be given in several divided doses.

Regular monitoring of the urine and blood count should be carried out before and during treatment. The blood pressure should be regularly monitored during administration of Zink-Trinatrium-pentetat (Zn-DTPA).

Long-term treatment should be carried out under regular monitoring of the radioactive nuclides and of the essential trace elements.

On acute poisoning, it is recommended that treatment should be initiated with the more potent trisodium calcium pentetate. Long-term treatment should then be carried out with the less toxic trisodium zinc pentetate.

The treatment of intoxications with Zink-Trinatrium-pentetat (Zn-DTPA) does not preclude other forms of therapies of intoxications, for instance gastrolavage, dialysis, plasma exchange, surgical resection of depots etc.

Other medicines and Zink-Trinatrium-pentetat (Zn-DTPA)

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

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 using this medicine.

Pregnancy

Insufficient experience exist in the use of Zink-Trinatrium-pentetat (Zn-DTPA) during pregnancy. The animal studies that have been carried out have not shown any indications of embryotoxic/teratogenic actions.

In case of pregnancy the risk of the poisoning and the risk of the administration of Zn-DTPA should be carefully considered. If the use of Zink-Trinatrium-pentetat (Zn-DTPA) during pregnancy is necessary for a vital indication, then the mineral balance should be monitored in order to provide the child with essential trace elements.

Breast-feeding

Breast-feeding should not be carried out in the presence of radionuclide uptake generally.

Driving and using machines

No effects are known to this day.

Zink-Trinatrium-pentetat contains sodium

One ampoule with 5 ml solution for injection contains 6.06 mmol (139.5 mg) sodium. To be taken into consideration by patients on a controlled sodium diet.

3. How to use Zink-Trinatrium-pentetat (Zn-DTPA)

You receive Zink-Trinatrium-pentetat as an intravenous injection or infusion.

Posology

Treatment of poisoning requires individual dosage depending on the symptoms of intoxication. Unless otherwise prescribed the usual dose is for

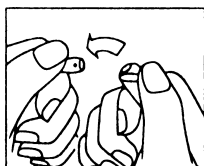
Adults: 1 ampoule per day
Children: 25 - 50 mg/kg body weight/day

The following dosage regimen is recommended for the therapy of adults:

- First week: 1 055 mg of Zn-DTPA on 5 days each
- Following 6 weeks: 1 055 mg of Zn-DTPA 2 to 3 times per week
- Following 6 weeks: therapy pause
- Further alternating 3 weeks therapy (1,055 mg of Zn-DTPA 2-3 times weekly) and 3 weeks therapy pause or 1 055 mg of Zn-DTPA i.v. every 2 weeks
- Depending on the individual case, the therapy pause can also be 4 to 6 months

Route and method of administration

Initially administer 1 055 mg of Zn-DTPA (about 15 mg/kg/d) in 20 ml of physiological saline solution or 5% glucose solution as a very slow i.v. injection (duration of the injection: about 15 min) or preferably as an infusion in 250 ml of the diluent over ½ to 2 h.



OPC ampoule

To open, turn so that the point faces upward and break off the neck with a downward movement.

You should drink well while using Zink-Trinatrium-pentetat (Zn-DTPA).

Duration of treatment

The duration of the treatment depends on the clinical and laboratory results (radionuclide excretion in the urine). As long as the excretion rate of the metals is increased by the administration of DTPA, the therapy should be continued.

The necessary treatment can be very protracted (in individual cases about several years) and requires a multitude of injections.

If you assume that more Zink-Trinatrium-pentetat (Zn-DTPA) was applied than it should

Symptoms of overdosage are not yet known.

If you assume that application of Zink-Trinatrium-pentetat (Zn-DTPA) has been forgotten

If you assume that the previous application has been forgotten address to professional health care staff.

If you stop using Zink-Trinatrium-pentetat (Zn-DTPA)

As there is a risk that the poisoning continues to exist please contact your doctor in any case before you interrupt or shorten the medical treatment.

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.

Possible side effects

Thrombophlebitic reactions have been described at a rapid intravenous injection.

Rare: may effect up to 1 in 1 000 people

- hypotension
- allergic reactions in the form of skin reactions

At repeated administrations of Zn-DTPA with too short regeneration intervals between the single ones, the following symptoms may occur: Delayed fever reaction, nausea, vomiting, diarrhoea, shiver, headaches, pruritus, muscular cramps.

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 Zink-Trinatrium-pentetat (Zn-DTPA)

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

Do not store above 25 °C.

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

6. Contents of the pack and other information

What Zink-Trinatrium-pentetat (Zn-DTPA) contains

- The active substance is: Trisodium zinc pentetate.
1 ampoule with 5 ml solution for injection contains 1 055 mg Trisodium zinc pentetate
- The other ingredients are: sodium hydroxide, pentetic acid, water for injections, zinc oxide.

What Zink-Trinatrium-pentetat (Zn-DTPA) looks like and content of the package

Zink-Trinatrium-pentetat (Zn-DTPA) is a clear, colourless to slightly yellowish solution for injection.

Zink-Trinatrium-pentetat (Zn-DTPA) is available in packages with 5 ampoules with 5 ml each.

Marketing Authorisation Holder

Heyl Chem.-pharm. Fabrik GmbH & Co. KG
Kurfürstendamm 178-179
10707 Berlin
Germany

Phone: +49 30 81696-0

email: info@hey-berlin.de

Fax: +49 30 81696-33

website: www.hey-berlin.de

Manufacturer

EVER Pharma Jena GmbH
Otto-Schott-Straße 15
07745 Jena
Germany

This leaflet was last revised in April 2018.

Properties

DTPA is a member of the synthetic polyaminopolycarboxylic acids, which are able to form stable compounds known as metal chelates with many metallic ions. The complexing agent binds to the metallic ions circulating in the body fluids or bound in the tissues with release of zinc and it promotes the excretion of the metallic ions into the urine. DTPA is considered nowadays to be the drug of choice for the removal of metallic radionuclides (e.g. Am, Pu, Cm, Cf, Bk) from the body.