Zink-Trinatrium-pentetat (Zn-DTPA)

Solution for injection
For the application in adults
Active pharmaceutical ingredient: Trisodium zinc pentetate

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. Perhaps you would like to read this again later.
- 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 symptoms are the same as yours
- If any of the listed side effects considerably impairs you or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

This package leaflet contains:
1. What Zink-Trinatrium-pentetat (Zn-DTPA) is and what it is used for?
2. What do you have to consider before you use Zink-Trinatrium-pentetat (Zn-DTPA)?
3. How does Zink-Trinatrium-pentetat (Zn-DTPA) have to be used?
4. Which side effects are possible?
5. How does Zink-Trinatrium-pentetat (Zn-DTPA) have to be stored?
6. Further information.

1. WHAT ZINK-TRINATRIUM-PENTETAT (ZN-DTPA) IS AND WHAT IT IS USED FOR?

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

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

2. WHAT DO YOU HAVE TO CONSIDER BEFORE YOU USE ZINK-TRINATRIUM-PENTETAT (ZN-DTPA)?

2.1 Do not use Zink-Trinatrium-pentetat (Zn-DTPA),
   - if you are allergic (hypersensitive) to DTPA or its salts or any of the other ingredients of Zink-Trinatrium-pentetat (Zn-DTPA);
• at hyperzincaemia 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.

2.2 At application of Zink-Trinatrium-pentetat (Zn-DTPA) with other drugs:
Please tell your doctor or pharmacist if you are taking/using or have recently taken/used other medicines even if the drugs are obtained without a prescription.

2.3 At application of Zink-Trinatrium-pentetat (Zn-DTPA) together with food and drinks:
During the application of Zink-Trinatrium-pentetat (Zn-DTPA) you should drink sufficiently.

2.4 Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking/applicating any medicine.

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

2.5 Driving and using machines
No special effects on drivers or the operation of machines are known to this day.

3. HOW SHOULD ZINK-TRINATRIUM-PENTETAT (ZN-DTPA) BE USED?

Please always use Zink-Trinatrium-pentetat (Zn-DTPA) exactly as your doctor has told you. Please consult your doctor or pharmacist if you are not sure.

3.1 Dosage
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

3.2 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.

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 from 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 be also 4 to 6 months.

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

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

The duration of the treatment depends on the clinical and laboratory results (radio-nuclide 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.

Please contact your doctor or pharmacist if you have the impression that the effect of Zink-Trinatrium-pentetat (Zn-DTPA) is too strong or too weak.

### 3.4 If you have used a larger quantity of Zink-Trinatrium-pentetat (Zn-DTPA) than you should:
Symptoms of overdosage are not known until today.

### 3.5 If you have forgotten an application of Zink-Trinatrium-pentetat (Zn-DTPA):
Do not use a double dose to make up for a forgotten dose. Continue with the given dosage.

### 3.6 If you stop the use of Zink-Trinatrium-pentetat (Zn-DTPA):
As there is a danger 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 product, please ask your doctor or pharmacist.

### 4. WHICH SIDE EFFECTS ARE POSSIBLE?

Like all medicines, Zink-Trinatrium-pentetat (Zn-DTPA) can cause side effects, although not everybody gets them.

The following frequency details are used as a base for the assessment of the side effects:
### 4.1 Possible side effects

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.

Hypotension as well as allergic reactions in the form of skin reactions are rare.

Thrombophlebitic reactions have been described at a rapid intravenous injection.

**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. By reporting side effects you can help provide more information on the safety of this medicine.

### 5. HOW IS ZINK-TRINATRIUM-PENTETAT (ZN-DTPA) TO BE STORED?

Do not use Zink-Trinatrium-pentetat (Zn-DTPA) after the expiry date which is stated on the label and on the package after "Expiry date:” The expiry date refers for the last day of the month.

Keep out of the reach and sight of children!

Do not store above 25 °C!

### 6. FURTHER INFORMATION

Regular monitoring of the urine and blood count should be carried out before and during treatment.

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.

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

The blood pressure should be regularly monitored during administration of Zink-Trinatrium-pentetat (Zn-DTPA).

6.1 What Zink-Trinatrium-pentetat (Zn-DTPA) contains:
The active pharmaceutical ingredient is Trisodium zinc pentetate.

1 ampoule with 5 ml injection solution contains 1,055 mg Trisodium zinc pentetate

The other ingredients are: sodium hydroxide, pentetic acid, water for injections, zinc oxide.

6.2 What Zink-Trinatrium-pentetat (Zn-DTPA) looks like and content of the package:
Zink-Trinatrium-pentetat (Zn-DTPA) is available in packages with 5 ampoules with 5 ml of clear injection solution each.

Marketing Authorisation Holder:

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Manufacturer:

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Otto-Schott-Straße 15
07745 Jena
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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: Zink-Trinatrium-pentetat (Zn-DTPA)

This package leaflet was revised last in December 2014.

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.