

Patient information leaflet

Drug Product

UNITHIOL

Trade name: Unithiol.

International nonproprietary name: None.

Chemical name: 2,3-dimercaptopropansulphonate sodium.

Appearance: Transparent solution, colourless or with pinkish-yellow tint, with slight smell of hydrogen sulfide.

Composition per one ampoule: *active ingredient:* unithiol – 250 mg; *excipient:* water for injection – q.s. to 5 ml.

Pharmaceutical form: Solution for intramuscular and subcutaneous injection 50 mg/ml.

Pharmaceutical group: Various drug products. Antidotes.

ATC code: V03AB.

Pharmacological action

The drug product acts as detoxicative agent. It eliminates a deficit of sulfhydryl groups. A mechanism of its action resembles mechanism of complexons action. Active sulfhydryl groups react with thiol poisons located in blood and tissues which results in formation of nontoxic complexes excreted with urine. Bonding of poisons leads to recovery of enzyme systems of a body affected by a poison. The drug product is effective as an antidote in cases of intoxication with arsenic compounds, salts of heavy metals, cardiac glycosides.

The drug product promotes decrease of pain syndrome, improvement of peripheral nervous system state and normalization of capillary permeability in patients suffering from diabetic polyneuropathy and secondary amyloidosis.

Indications

- ~ Acute and chronic intoxication with arsenic, mercury, chrome, bismuth compounds and cardiac glycosides;
- ~ Hepatolenticular disease (Wilson-Westphal-Konovalov's disease);
- ~ Diabetic polyneuropathy;
- ~ Alcohol addiction (as a part of a complex therapy).

Dosage and mode of administration

Unithiol should be administered intramuscularly or subcutaneously for a treatment of *acute or chronic intoxication with arsenic and mercury compounds* (5-10 ml of solution with concentration 50 mg/ml). The treatment is to be started as early as possible.

In case of *poisoning with arsenic compounds* injections are made every 6-8 hours during first 24 h period, 2-3 injections every 8-12 hours during second 24 h and 1-2 injections per further days.

In case of *poisoning with mercury salts* the treatments is performed with the same dosage regimen for not less than 6 days.

In case of poisoning with *cardiac glycosides* 5 or 10 ml of Unithiol solution with concentration 50 mg/ml should be injected intramuscularly or subcutaneously during first two days. Injection is carried out 3-4 times per day and afterwards 1-2 times per day until termination of a cardiotoxic action is observed.

In patients with *hepatolenticular degeneration* 5-10 ml of 50 mg/ml solution should be administered intramuscularly on a daily basis or every second day. Treatment schedule – 25-30 injections with a 4 months interval between courses.

In patients with *diabetic polyneuropathy* 5 ml of 50 mg/ml solution should be administered daily during 10 days.

In patients with *alcohol addiction* 3-5 ml of 50 mg/ml solution is administered intramuscularly 2-3 times per week.

Side Effects

Nausea, vomiting, dizziness, tachycardia, skin covering pallor, increased blood pressure, anxiety.

In the case of appearance of mentioned adverse reactions and side effects not listed in this leaflet consult your doctor.

Contraindications

Hypersensitivity, severe liver diseases, arterial hypertension.

Overdose

Symptoms: increased blood pressure.

Treatment: cancellation of the drug product administration, symptomatic therapy.

Precautions

Unithiol injection in case of acute poisoning does not exclude administration of other therapeutic interventions (gastric lavage, oxygen inhalation, glucose injection).

Administration in children. Data on efficacy and safety of Unithiol administration in children is absent.

Administration in the period of pregnancy and lactation. As for data on efficacy and safety of Unithiol administration in pregnant and lactating women is absent administration during pregnancy and lactation period is not recommended.

Impact on driving capacity and managing other potentially hazardous mechanisms. Due to the fact that during Unithiol administration adverse effects (dizziness, increased blood pressure, tachycardia) may appear it is not recommended to drive and to occupy with other activities requiring boosting attention.

Interaction with other drug products

Administration of Unithiol with drug products containing heavy metals and alkalies is not recommended as far as in this case decomposition of Unithiol takes place.

Storage conditions

Store in protected from light place at temperature below 25 °C. Keep out of reach of children.

Shelf life

5 years.

Do not use after expiration of a shelf life specified on a package.

Package

Ampoules of 5 ml in a package No. 10.

Prescription status

Prescription only medicine.

Manufacturer

"Belmedpreparaty" RUE

30, Fabritsius Str.,

Minsk, 220007,

Republic of Belarus.

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