

Package leaflet: Information for the user

Dimaval® (DMPS) 100 mg Hartkapseln

Active substance: (RS)-2,3-Bis(sulfanyl)propane-1-sulfonic acid, sodium salt 1 H₂O



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 it is in this leaflet

1. What Dimaval (DMPS) 100 mg Hartkapseln is and what it is used for
2. What you need to know before you take Dimaval (DMPS) 100 mg Hartkapseln
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1. What Dimaval (DMPS) 100 mg Hartkapseln is and what it is used for

Dimaval (DMPS) 100 mg Hartkapseln contains (RS)-2,3-Bis(sulfanyl)propane-1-sulfonic acid, sodium salt 1 H₂O and is used as an antidote for treatment of poisoning with heavy metals.

Dimaval (DMPS) 100 mg Hartkapseln is approved for the treatment of

- clinically manifest chronic and acute poisonings with mercury (inorganic and organic compounds, vapour and metallic mercury),
- chronic poisoning with lead

2. What you need to know before you take Dimaval (DMPS) 100 mg Hartkapseln

Do not take Dimaval (DMPS) 100 mg Hartkapseln

- if you are allergic to the active substance DMPS, its salts or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Dimaval (DMPS) 100 mg Hartkapseln.

Therapy must be interrupted if allergic reactions appear interrupt, otherwise a Stevens-Johnson syndrome may occur.

These initially appear as reddish target-like spots or circular patches often with central blisters on the trunk. The rash may progress to widespread blistering or peeling of the skin. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and red and swollen eyes (conjunctivitis). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms (headache, fever, limb pain).

If you develop a rash or any other of these skin symptoms, **stop taking** Dimaval (DMPS) 100 mg Hartkapseln, **seek urgent advice from a doctor** and tell him that you are taking Dimaval (DMPS) 100 mg Hartkapseln.

The administration of Dimaval (DMPS) 100 mg Hartkapseln does not preclude the use of other forms of treatment of poisoning, for instance gastric lavage, dialysis, plasma exchange, etc.

Long-term treatment should be accompanied by periodic monitoring of the excretion of the toxic metal and essential trace elements via the urine.

Other medicines and Dimaval (DMPS) 100 mg Hartkapseln

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

Dimaval (DMPS) 100 mg Hartkapseln should not be taken simultaneously with mineral preparations. A possible DMPS-mineral chelate formation may lead to loss of effectivity of DMPS already in the intestines. For the same reason DMPS should be taken at least 1 hour prior to meals.

The simultaneous administration of charcoal and Dimaval (DMPS) 100 mg Hartkapseln should be avoided.

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.

Pregnancy

DMPS did not show any teratogenic effects in animal experiments. Although adequate experience is not yet available in humans, pregnant women do not need to be generally excluded from DMPS therapy. The risk of poisoning and the risk of drug treatment should be carefully considered. In the case of treatment of pregnant women with DMPS, the mineral balance, especially of zinc, should be carefully monitored. It is known that zinc deficiency caused by chelating agents may have a teratogenic effect.

Breast-feeding

Heavy metal contaminated mothers should not breast feed in general.

Driving and using machines

No consequences are known to this day.

3. How to take Dimaval (DMPS) 100 mg Hartkapseln

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Posology

The dose is always adjusted according to type and severity of poisoning.
The usual dose for adults is:

- *in cases of acute poisoning*
initially a daily dose of 12 to 24 capsules in single doses administered evenly throughout the day (e.g. 12 x 1 to 2 capsules per day).
- *in cases of chronic poisoning*
3 to 4 capsules Dimaval (DMPS) 100 mg Hartkapseln daily. In severe chronic poisoning, the daily dose may be increased. The daily dose should be taken as single doses of 1 to 2 capsules spread evenly throughout the day.

Route and method of administration

For oral use.

Please take the hard capsules 1 hour prior to meals with fluids.

Duration of treatment

The duration of treatment is always dependent on clinical and analytical findings (excretion of heavy metal in the urine).

If you take more Dimaval (DMPS) 100 mg Hartkapseln than you should

Overdosing with orally administered DMPS is not known to this time. After intravenous administration of DMPS, cardiovascular effects such as fall in blood pressure, weakness, or nausea may occur on overdose. DMPS can be removed by dialysis.

If you forget to take Dimaval (DMPS) 100 mg Hartkapseln

Do not take a double dose to make up for a forgotten dose. Continue with the prescribed dosage.

If you stop taking Dimaval (DMPS) 100 mg Hartkapseln

If you interrupt or shorten the medical treatment the risk of poisoning continues. Please contact your doctor before you do so.

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.

Some side effects can be serious. If you notice any of the following signs contact a doctor immediately.

Very rare: may affect up to 1 in 10 000 people

- severe, allergic skin rashes (e. g. Erythema exsudativum multiforme, Stevens-Johnson syndrome). For further information see section 2 "Warnings and precautions".
- Following the administration of the preparation, the absorbed or ingested mercury is mobilised in the body. This very rarely triggers renal failure with very low urine production as the clinical symptom of mercury poisoning.

In cases of hypersensitivity reactions contact a doctor immediately.

Other possible side effects

Uncommon: may affect up to 1 in 100 people

- Shivers, fever or skin reactions -probably of allergic nature- such as itching or rashes (exanthema) may occur; they usually disappear when the treatment is discontinued.

Rare: may affect up to 1 in 1 000 people

- Nausea
- Reduction of white blood cells (leukopenia)

Very rare: may affect up to 1 in 10 000 people

- higher concentration of certain enzymes (transaminases)

If Dimaval (DMPS) 100 mg Hartkapseln is applied for a longer period, it may affect the mineral balance, primarily of the elements zinc and copper.

In the case of mineral deficiency, substitution of trace elements is necessary.

In case of all other side effects Dimaval (DMPS) 100 mg Hartkapseln treatment should be discontinued. In addition, it may be necessary to start a symptomatic therapy.

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 Dimaval (DMPS) 100 mg Hartkapseln

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

Do not store above 25 °C.

Store in the original package in order to protect from moisture.

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

6. Contents of the pack and other information

What Dimaval (DMPS) 100 mg Hartkapseln contains

- The active substance is: (RS)-2,3-Bis(sulfanyl)propane-1-sulfonic acid, sodium salt 1 H₂O. 1 hard capsule contains 108,56 mg (RS)-2,3-Bis(sulfanyl)propane-1-sulfonic acid, sodium salt 1 H₂O corresponding to 100 mg DMPS sodium salt.
- The other ingredients are: copovidone, hypromellose, maize starch.

What Dimaval (DMPS) 100 mg Hartkapseln looks like and contents of the pack

Dimaval (DMPS) 100 mg Hartkapseln consists of transparent hard capsules containing a white substance.

It is available in packs containing 3, 9 or 20 hard capsules in blister packs.

Marketing Authorisation Holder

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Properties

(RS)-2,3-Bis(sulfanyl)propane-1-sulfonic acid, which is contained in Dimaval (DMPS) 100 mg Hartkapseln in the form of a sodium salt, is a complexing agent from the group of vicinal dithiols. By means of the two adjacent SH-groups it forms stable complexes with various heavy metals. These are mainly excreted via the renal route with the urine. In this way DMPS stimulates the elimination of heavy metals from space outside body cells, i.e. extracellular space. However, the toxicity of heavy metals is already reduced by complex formation, since heavy metals in the organism can no longer block the SH-groups in vital enzymes.