Package leaflet: **Information for the patient**

Dimaval® 250 mg DMPS-Na/5 ml Solution for injection
Active substance: (RS)-2,3-Bis(sulfanyl)propane-1-sulfonic acid, sodium-salt 1 H_2O

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 your 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

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2. What you need to know before you use Dimaval
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1. What Dimaval is and what it is used for

Dimaval contains (RS)-2,3-Bis(sulfanyl)propane-1-sulfonic acid, sodium salt 1 H_2O and is used as an antidote for treatment of mercury poisoning.

Dimaval is used for cases of acute mercury poisoning (metallic, vapour, inorganic or organic compounds), if application by mouth or treatment by means of a gastric aspiration tube are not possible.

2. What you need to know before you use Dimaval

Do not use Dimaval
- if you are allergic to the active substance of Dimaval, 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 using Dimaval.

If allergic reactions to the active substance appear interrupt therapy immediately, otherwise a Stevens-Johnson syndrome may occur. This appears initially 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 other of these skin symptoms, **stop using** Dimaval, **seek urgent advice from a doctor** and tell him that you are using Dimaval.

Patients with impaired renal function (renal insufficiency) can only be treated with the drug if dialysis is performed concurrently.

Particular caution is advisable in patients with symptoms of allergic asthma.

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

If Dimaval and essential trace elements such as zinc and copper are applied concurrently, the pharmaceuticals may neutralize each other's efficacy. For this reason it is advisable to perform any required substitution of trace elements at some later time.

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
There is no sufficient empirical data available on the application of Dimaval to pregnant women. Animal trials have not revealed any toxicity for the fetus or a teratogenic potential.

As a precautionary measure, it is preferable to avoid the use of Dimaval during pregnancy. However, if the application of Dimaval during pregnancy is necessary for vital reasons, the mineral balance, especially that of zinc and copper, must be monitored in order to ensure that the fetus is supplied with essential trace elements, for zinc deficiency caused by a chelating agent is known to be teratogenic.

Breast-feeding
In principle, breast-feeding should not be carried out in the presence of heavy-metal poisoning.

Driving and using machines
No consequences are known to this day.

Dimaval contains sodium.
This medicine contains 27.4 mg sodium (main component of cooking/table salt) in each ampoule. This is equivalent to 1.4 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Dimaval

You receive Dimaval as an intravenous or intramuscular injection.

Posology
The dosage is always adjusted to the type and severity of poisoning.

Adults
Unless otherwise prescribed, the usual dose at acute poisoning is:

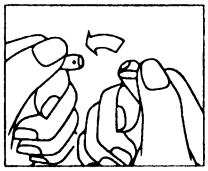
Day of treat-ment	Single dose		Dosing interval between single doses	Maximum daily dose	
	DMPS-Na	Number of ampoules		DMPS-Na	Number of ampoules
1	250 mg	1	3-4 hours	1,500-2,000 mg	6-8
2	250 mg	1	4-6 hours	1,000-1,500 mg	4-6
3	250 mg	1	6-8 hours	750-1,000 mg	3-4
4	250 mg	1	8-12 hours	500-750 mg	2-3

The content of one ampoule with 271.4 mg DMPS sodium salt monohydrate corresponds to 250 mg DMPS sodium salt (DMPS-Na).

Subsequent days: Depending on the clinical condition, the contents of one ampoule of Dimaval should be administered once to three times (corresponding to 250 – 750 mg DMPS-Na per day) daily. As an alternative, the patient may be switched to the oral pharmaceutical form of DMPS-Na.

Route and method of administration
The solution for injection may be administered by intravenous or intramuscular application.
In the case of intravenous injection, Dimaval must be administered slowly, i.e. over a period of three to five minutes (see section 4).

However, the solution for injection should only be administered to patients who cannot take the pharmaceutical by mouth.
Dimaval solution for injection must not be mixed with other solutions for injection.



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

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

If you assume that more Dimaval was applied than it should
Apart from cardio-vascular reactions (see section 4) overdosage of Dimaval may cause necrosis on the injection site.

The active substance can be removed by dialysis.

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

If you stop using Dimaval
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 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 reactions (such as erythema exsudativum multiforme, Stevens-Johnson syndrome). For further information see section 2, subsection “Warnings and precautions”.
- Following the administration of this medicine, the absorbed or ingested mercury is mobilised in the body. This may trigger renal failure with very low urine production as a 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 occasionally; they usually disappear when the treatment is discontinued.

Very rare: may affect up to 1 in 10 000 people
- Asthma attack in asthma patients during or immediately after the injection
- Increased levels of certain enzymes (transaminases)
- Painful injection site, unpleasant hydrogensulfide odour, white cell count reduced by 50%, dysgeusia, stenocardia, abdominal complaints, loss of appetite.

Particularly if Dimaval is injected too quickly, cardiovascular reactions may occur, usually a short while after the injection (5 – 10 minutes). They become manifest as a drop in blood pressure, nausea, vertigo, weakness.

If Dimaval is applied for a longer period, it may affect the mineral balance, primarily that of the elements zinc and copper.

In case of mineral deficiency, substitution of trace elements is necessary. Dimaval treatment should be discontinued if you develop other adverse reactions. In addition, it may be necessary to introduce 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 Medizin-produkte, 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

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

Do not store above 25 °C.

Opened ampoules must not be stored; their contents must not be used but be discarded.

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

Do not throw away any medicines via wastewater (e.g., via toilet or washbasin). Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment. You can find further information at www.bfarm.de/arzneimittelentsorgung.

6. Contents of the pack and other information

What Dimaval contains
- The active substance is (RS)-2,3-Bis(sulfanyl)propane-1-sulfonic acid, sodium salt 1 H_2O.
  One ampoule containing 5 ml injection solution contains 271.4 mg (RS)-2,3-Bis(sulfanyl)propane-1-sulfonic acid, sodium salt 1 H_2O (DMPS sodium salt 1 H_2O) corresponding to 250 mg (RS)-2,3-Bis(sulfanyl)propane-1-sulfonic acid, sodium salt (DMPS-Na)

- The other ingredient is: Water for injection.

How Dimaval looks like and contents of the pack
Dimaval is a clear, coulourless solution for injection.

It is available in packages with 1 ampoule of 5 ml solution for injection and with 5 ampoules of 5 ml solution for injection each.

Marketing authorisation holder
Heyl Chem.-pharm. Fabrik
GmbH & Co. KG
Kurfürstendamm 178-179
10707 Berlin
Germany
Phone: +49 30 81696-0 Email: info@heyl-berlin.de
Fax: +49 30 81696-33 Website: www.heyl-berlin.de

Manufacturer
Streuli Pharma AG
Bahnhofstrasse 7
8730 Uznach
Switzerland

Final Release
IL- CSM Clinical Supplies Management GmbH
Marie-Curie-Str. 8
79539 Lörrach
Germany

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Properties
(RS)-2,3-Dis(sulfanyl)propane-1-sulfonic acid, previously known as (RS)-2,3-Di-mercapto-1-propanesulfonic acid (DMPS), which is present in Dimaval 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. extracelluar 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.