

INFORMED CONSENT

ABOUT DMPS:

Dimercapto-propane-sulfonic acid (DMPS) is an antidote for poisoning with various heavy/toxic metals such as mercury, arsenic, lead and copper. DMPS is available in the United States and Canada as a bulk chemical and is prepared into either oral or injectable form by a compounding pharmacist when presented with a prescription from a physician.

There are only 3 manufacturers of this chemical in the world. It is produced in Russia, China and Germany. In this office we use/prescribe only German manufactured DMPS. The German manufacturer follows western manufacturing guidelines and they are well known for their quality. They have also complied with the U.S. FDA in registering as a bulk chemical importer and their manufacturing facility in Germany has been inspected by the U.S. FDA.

DMPS is an approved treatment in Germany for acute and chronic poisoning from mercury and lead and has been used there for more than 20 years. Its use in the US is considered experimental.

DMPS IS NOT FDA APPROVED IN THE UNITED STATES

ALTERNATIVE TREATMENTS:

There are no medications/antidotes in the US or Canada that are FDA approved for mercury.

Currently the other available chelators/antidotes to toxic metals are:

BAL (British anti-lewisite) – Available only as an injectable for deep muscle injection. It has several side effects and is quite painful. It is not used much anymore having been replaced by its analogs, DMSA and DMPS.

DMSA – Is FDA approved only for lead poisoning in children. Is available in oral form only. Reports in the scientific literature reveal that DMSA may redistribute methyl mercury to the brain. For additional information on this drug, consult a Physicians' Desk reference, under the brand name "Chemet".

EDTA – The injectable form is FDA approved for lead poisoning. Contraindicated for mercury. May redistribute mercury to the brain. Available in injectable and oral forms.

d-Penicillamine – Is FDA approved as an antidote for copper poisoning. Binds to mercury also. Persons who are allergic to penicillin may also react to this drug.

DMPS is a compounded medication. Only a compounding pharmacist that stocks this chemical can fill a prescription for this drug. Not all pharmacies compound medications. We will give you a list of pharmacies that can fill prescriptions for oral DMPS. Intravenous DMPS, when and if needed, is obtained by this office from a competent, licensed pharmacy that is properly equipped to make sterile solutions for injection.

How and when we use DMPS:

DMPS is used when an accumulation of, or poisoning with a toxic metal (mercury, lead, arsenic, copper) is suspected as a contributing cause of your current conditions/complaints. This is determined by answers you have given on your history and medical evaluation forms, exposure history and past and current symptoms and initial baseline laboratory tests.

The initial administration of DMPS is for conducting a challenge test to help determine if there is an accumulation of toxic metals in body tissues. A challenge test has 3 steps: 1.) The collection of urine output for a specific period of time, usually 6, 12 or 24 hours. This is called a baseline study. 2.) Administration of a chelating agent (in this instance DMPS is used) and 3.) A second timed urine specimen is collected immediately after the drug is administered.

The urine collections are tested by a laboratory to determine the heavy metal content. The values from the baseline urine and the urine collected after the DMPS are compared. This helps to determine if there is an accumulation of toxic metals stored in organs or other tissues in the body. If indicated, treatment is instituted and periodically urine (and blood) is collected to monitor progress.

Possible Reactions and side Effects that may occur with the use of DMPS:

DMPS stays in the body for only a short period of time depending on how it is taken but all of it is excreted within 24 hours of administration. DMPS does not build up or accumulate in the body. It does not cross the blood brain barrier, so it cannot redistribute any metal into the brain as has been demonstrated with some chelators.

As with all drugs, it does have the potential for some side effects. The more common side effects are:

- Skin reactions including itching and rash
- Nausea
- Dizziness
- Fever
- Weakness
- Elevated body temperature
- Shivering and fever
- Sudden drop in blood pressure. (with IV administration only).

These reactions occur mostly with long term therapy. It is also not clear if some of these reactions are actually due to the mobilization of a heavy metal(s) (arsenic is known to cause skin rash) or a pre-existing mineral deficiency.

DMPS also binds to some trace minerals such as zinc. Trace mineral levels may become depleted in some people on long term therapy. We will check your mineral levels in blood and urine prior to administering DMPS. We will also check your kidney function prior to administration of DMPS. (This is standard procedure for safety when using any chelating drug).

If a zinc deficiency is present, DMPS may exacerbate the symptoms of this mineral deficiency. In this instance we wait to administer the DMPS until this deficiency can be resolved.

Another side effect that occurs in almost all instances is the odor of rotten eggs which will affect the odor of urine and other body secretions for the time that the drug is circulating in the body. This is due to the sulfur nature of DMPS.

A sudden drop in blood pressure can be experienced if the IV form of DMPS is given too quickly (in less than 5 minutes). The symptoms include dizziness weakness, nausea, heart palpitations and a feeling of pressure in the chest. At this office the IV form is given over a period of 10 to 15 minutes depending on the dose and volume of drug, which is calculated by your body weight.

The most common effects reported with the use of oral DMPS are nausea and skin rash.

Allergic reactions and side effects generally resolve after withdrawal from treatment. No cases of anaphylactic shock have ever been reported with the use of DMPS.

Some people experience some discomfort at the injection site during the IV. This is due to the low pH of the solution. Oral administration is the preferred and recommended route of administration. Intravenous injection is used in special circumstances when oral application cannot be used. When these particular circumstances arise in an individual case, the person is informed and given the option of the injections.

DMPS is contraindicated in people who have a known hypersensitivity to the substance or its' salts. There is higher incidence of side effects in people with asthmatic symptoms or severe allergic symptoms. Chelating agents are not advised to be used in pregnant or lactating (breast feeding) females. It is important to drink a lot of water as instructed during treatment with this drug whether on the oral form or the

injection. This is to help the body eliminate those toxic metals that DMPS binds to and to help guard against any damage to the kidneys that may result from the metal that is excreted through them.

There may or may not be medical benefits from taking DMPS.

If you decide at a later time that you no longer want to receive this treatment, you may discontinue the treatment and revoke this informed consent. If at some point in the treatment plan it becomes evident that DMPS is not benefiting you, I will re-evaluate your case and discuss the findings and options with you at that time. If you have not reviewed the **Proposed Treatment Plan** prepared for you, please do so at this time before signing this consent.

IF YOU HAVE ANY QUESTIONS ABOUT DMPS OR THIS PROCEDURE, PLEASE **write them on the reverse of this page and ASK THEM NOW.**

For additional information on DMPS, you may visit WWW.DMPS.CC

Please acknowledge that you have read each of the statements below by initialing on the line to the left of the item.

I, _____ being of the age of legal consent in the state of _____ and being of sound mind and fluent in English, have read all of the above information regarding DMPS and understand the content and meaning.

_____ I have reviewed the proposed treatment plan and understand its content and the laboratory tests and treatment schedule.

_____ I understand that DMPS is not an FDA approved finished form drug in the US and that the preparation has to be made for me by a compounding pharmacy. I understand the potential risks involved in taking the drug DMPS as they are outlined in this consent form.

_____ All of my questions about this treatment have been answered to my satisfaction.

_____ I agree to this treatment according to the plan devised for me and request that Dr. Michael Gurevich administer this treatment to me.

_____ The doctor nor anyone on the staff of this office has offered me any inducement or guarantee of improvement or cure, that has influenced my decision to accept this treatment plan.

_____ I understand that I may withdraw from this treatment plan and revoke this consent at any time.

For females only: I am sure that I am not pregnant, nor am I planning to attempt pregnancy during my challenge test/treatment with this drug. If I suspect pregnancy, I agree to report this immediately to the Doctor and agree to a pregnancy test. I understand and agree to immediately terminate this treatment if a pregnancy occurs.

Initials: _____

Patient Signature: _____ Date: _____ Print Name: _____

Witness Signature: _____ Date: _____ Print Name: _____