

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

TREOSULFAN FOR INJECTION

treosulfan for injection

Read this carefully before you start taking **TREOSULFAN FOR INJECTION** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TREOSULFAN FOR INJECTION**.

Serious Warnings and Precautions:

Bone Marrow Suppression: The intended effect of TREOSULFAN FOR INJECTION is to suppress the bone marrow. This is to prepare you for a blood stem cell transplant from a donor. This is a very serious and potentially fatal condition. The only way to recover from this severe bone marrow suppression is with a blood stem cell transplant. Your healthcare professional will closely monitor the health of your blood cells while you are taking TREOSULFAN FOR INJECTION and after your transplant. Low blood cell levels will last longer in children and adolescents than in adults. If you experience any of the following symptoms tell your healthcare professional immediately:

- symptoms of infections including; fever, chills, sore throat, mouth sores
- weakness, fatigue
- easy bruising, bleeding of the nose, gums or mouth, tiny red spots on the skin
- rash
- shortness of breath
- pale skin, lips and nail beds

What is TREOSULFAN FOR INJECTION used for?

TREOSULFAN FOR INJECTION is used together with fludarabine to prepare patients for a blood stem cell transplant from a donor:

- in adults with the blood cancers Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS) who are not able to tolerate the standard preparation therapies,
- in children and adolescent older than one year of age with AML or MDS.

How does TREOSULFAN FOR INJECTION work?

TREOSULFAN FOR INJECTION contains the medicinal ingredient treosulfan, which belongs to a group of medicines called alkylating agents. TREOSULFAN FOR INJECTION is used to prepare patients for blood stem cell transplant. TREOSULFAN FOR INJECTION destroys your bone marrow cells. This allows for the transplant of new blood stem cells from a donor which leads to the production of healthy blood cells.

What are the ingredients in TREOSULFAN FOR INJECTION?

Medicinal ingredients: treosulfan

Non-medicinal ingredients: None

TREOSULFAN FOR INJECTION comes in the following dosage form:

lyophilized powder 5 g / vial.

Do not use TREOSULFAN FOR INJECTION if you:

- are allergic (hypersensitive) to treosulfan
- have an untreated infection
- have severe heart, lung, liver or kidney problems
- were born with a DNA breakage repair disorder, a condition that reduces the ability to repair DNA (which carries your genetic information), such as Fanconi anemia
- are pregnant, or think you may be pregnant
- have recently had, or are going to have, a live vaccine, such as the MMR (measles, mumps, rubella) or chickenpox vaccines

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TREOSULFAN FOR INJECTION. Talk about any health conditions or problems you may have, including if you:

- have heart or lung problems
- are breastfeeding. You must not breastfeed while you are taking TREOSULFAN FOR INJECTION

Other warnings you should know about:

- **Cancer Risk:** TREOSULFAN FOR INJECTION may increase the risk of having another cancer in the future.
- **Driving and Using Machines:** TREOSULFAN FOR INJECTION can cause nausea, vomiting and dizziness which may affect your ability to drive or use machines. Wait to see how you respond to TREOSULFAN FOR INJECTION before you drive or use machines.
- **Mouth Sores:** Inflammation of the tissues in the mouth and mouth sores are common side effects of TREOSULFAN FOR INJECTION. The following can help reduce inflammation and sores in the mouth:
 - Practicing good oral hygiene (keeping your mouth and teeth clean).
 - Using mouthwashes that kill bacteria (antimicrobial) or form a barrier of protection on the tissue.
 - Applying ice to the tissues in the mouth. This will reduce the blood flow and also the amount of TREOSULFAN FOR INJECTION that reaches these tissues.
- **Blood Tests:** TREOSULFAN FOR INJECTION is a cell-killing medicine that is used to decrease the number of blood cells. At the recommended dose, this is the desired effect. You will have regular blood tests during treatment to check that your blood cell counts do not fall too low. Your healthcare professional will also do blood tests to monitor the health of your liver and heart and to check for other side effects. Your healthcare professional will decide when to perform blood tests and interpret the results.
- **Serious Heart and Lung Side Effects:** TREOSULFAN FOR INJECTION can cause serious heart and lung side effects. You will be monitored for signs of these side effects. See the **Serious Side Effects and What To Do About Them** table below, for more information.
- **Birth Control for Men and Women:** Men and women must use effective birth control while taking TREOSULFAN FOR INJECTION and for 6 months after their last dose. You must not get pregnant or father a child while taking TREOSULFAN FOR INJECTION or for 6 months after. This is because TREOSULFAN FOR INJECTION may harm your/your female partner's unborn baby. Talk to your healthcare professional about the birth control options that are right for you.

- **Fertility in Men and Women:** TREOSULFAN FOR INJECTION may make you infertile. This means you might not be able to get pregnant or father a child after taking TREOSULFAN FOR INJECTION. In women, TREOSULFAN FOR INJECTION may cause you to stop ovulating and may also stop your period which may cause symptoms of menopause even if you are pre-menopausal. You should discuss ways to preserve your fertility with your healthcare professional before you start taking TREOSULFAN FOR INJECTION. Male patients should consider sperm preservation before they start taking TREOSULFAN FOR INJECTION.
- **Diaper rash:** Diaper rash with skin ulceration of the area around the anus may occur in children wearing diapers. This is because TREOSULFAN FOR INJECTION passes out in the urine and can damage the skin. Diapers should be changed frequently during the 6–8 hours after each dose of TREOSULFAN FOR INJECTION.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take TREOSULFAN FOR INJECTION:

TREOSULFAN FOR INJECTION will be given to you by a healthcare professional experienced in preparing patients for a blood stem cell transplant. It is given by drip (infusion) into a vein before the blood stem cell transplant.

Usual dose:

Note: TREOSULFAN FOR INJECTION manufactured by Marcan Pharmaceuticals Inc. is only available in the 5 g/vial strength.

TREOSULFAN FOR INJECTION is used together with fludarabine. Your healthcare professional will decide on your dose based on your height and weight. You will receive TREOSULFAN FOR INJECTION as a 2 hour infusion once a day for 3 days before the blood stem cell transplant. You will also receive fludarabine as a 30 minute infusion once a day for 5 days before the blood stem cell transplant. The schedule will look like this:

Day -6: fludarabine

Day -5: fludarabine

Day -4: TREOSULFAN FOR INJECTION followed by fludarabine

Day -3: TREOSULFAN FOR INJECTION followed by fludarabine

Day -2: TREOSULFAN FOR INJECTION followed by fludarabine

Day -1: no medicine

Day 0: blood stem cell transplant

Overdose:

If you think you, or a person you are caring for, have taken too much TREOSULFAN FOR INJECTION, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

You will be given TREOSULFAN FOR INJECTION in the hospital under supervision of your healthcare professional however, if you think you have missed a dose of TREOSULFAN FOR INJECTION, tell your healthcare professional as soon as possible.

What are possible side effects from using TREOSULFAN FOR INJECTION?

These are not all the possible side effects you may feel when taking TREOSULFAN FOR INJECTION. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- decreased appetite, indigestion
- constipation
- weight gain
- tiredness
- trouble sleeping (insomnia)
- headache
- dizziness
- flushing
- pain in the arms and legs, back pain
- muscle pain
- dry eyes

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Bone marrow suppression: infections (fever, chills, sore throat, mouth ulcers), weakness, fatigue, easy bruising, bleeding of the nose, gums or mouth, tiny red spots on the skin, rash, shortness of breath, pale skin, lips and nail beds		✓	
Stomatitis: inflammation of the tissues in the mouth, mouth pain, mouth sores and/or ulcers, bleeding in the mouth		✓	
Gastrointestinal problems: diarrhea, nausea, vomiting, stomach pain	✓		
Alopecia: hair loss		✓	
COMMON			
Sepsis (infection of the blood): fever, chills, very low body temperature, urinating less often, fast heartbeat, nausea, vomiting, diarrhea, fatigue, blotchy or discoloured skin, can lead to shock and death			✓
Heart rhythm problems: heartbeat is irregular, too fast or too slow		✓	
High blood pressure: headache, shortness of breath	✓		

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
Low blood pressure: lightheadedness, dizziness and fainting, especially when you go from lying or sitting to standing	✓		
Difficulty swallowing	✓		
Skin problems: rash with flat or raised red bumps, redness, itching, dry skin, skin ulcers, blisters, changes in skin colour	✓		
Bone pain	✓		
Kidney problems: decreased urination, blood in the urine, nausea, vomiting, swelling of the arms or legs, fatigue		✓	
Edema: swelling of the hands or feet	✓		
UNCOMMON			
High blood sugar: frequent urination, thirst, hunger	✓		
Nervous system problems (such as bleeding in the brain or brain damage): weakness or paralysis of arms, legs or face, difficulty speaking, severe headache, seeing, feeling or hearing things that are not there, loss of consciousness, confusion, disorientation, trembling, seizures, muscle twitching			✓
Confusion	✓		
Peripheral neuropathy (problems in the nerves of the arms or legs): numbness, reduced or increased sensitivity, tingling, burning pain	✓		
Vertigo: feeling of spinning or whirling	✓		
Lung problems (inflammation of the lung, fluid around the lung): shortness of breath, dry cough, fatigue, feeling of heaviness or tightness in the chest, chest pain		✓	
Liver problems (including liver failure): yellowing of the whites of the eyes or skin, itchiness, dark urine, pale stool, weight gain, abdominal swelling and pain, loss of appetite, shortness of breath, disorientation or confusion (more common		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
in children and adolescents)			
Chest pain	✓		
UNKNOWN FREQUENCY Allergic reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
Gastrointestinal bleeding: blood in the stool, vomiting blood			✓
Injection site reaction: pain, redness or swelling at the injection site	✓		
Heart failure: shortness of breath on exertion or when lying down, fatigue, weakness, swelling in your legs, ankles and feet, fast or irregular heartbeat, cough or wheezing with blood-tinged phlegm		✓	
Heart attack: chest pain, shortness of breath, weakness, lightheadedness, pain or discomfort in the jaw, neck, back, shoulder or arm			✓
Pulmonary embolism (blood clot in the lung): shortness of breath, sudden chest pain especially when breathing in, coughing up blood			✓
Thrombosis (blood clot): swelling, pain, redness and warmth in an arm or leg		✓	
Fainting		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

TREOSULFAN FOR INJECTION will be stored by your healthcare professional.

If you want more information about TREOSULFAN FOR INJECTION:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.marcanpharma.com, or by calling 1-855-627-2261.

This leaflet was prepared by Marcan Pharmaceuticals Inc.

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