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Source : U.S. National Library of Medicine

URL of this page: <https://medlineplus.gov/druginfo/meds/a608019.html>

Mitoxantrone Injection

pronounced as (mye toe zan' trone)

IMPORTANT WARNING:

Mitoxantrone should be given only under the supervision of a doctor with experience in the use of chemotherapy medications.

Mitoxantrone may cause a decrease in the number of white blood cells in the blood. Your doctor will order laboratory tests regularly before and during your treatment to check whether the number of white blood cells in your body has decreased. If you experience any of the following symptoms, call your doctor immediately: fever, chills, sore throat, cough, frequent or painful urination, or other signs of infection.

Mitoxantrone injection may cause damage to your heart at any time during your treatment or months to years after your treatment has ended. This heart damage can be serious and may cause death and can occur even in people without any risks for heart disease. Your doctor will examine you and perform certain tests to check how well your heart is working before beginning treatment with mitoxantrone and if you show any signs of heart problems. If you are using mitoxantrone injection for multiple sclerosis (MS; a condition in which the nerves do not function properly, causing symptoms such as weakness; numbness; loss of muscle coordination; and problems with vision, speech, and bladder control), your doctor will also perform certain tests before each dose of mitoxantrone injection and yearly after you have completed your treatment. These tests may include an electrocardiogram (ECG; test that records the electrical activity of the heart) and an echocardiogram (test that uses sound waves to measure your heart's ability to pump blood). Your doctor may tell you that you should not receive this medication if the tests show your heart's ability to pump blood has decreased. Tell your doctor if you have or have ever had any type of heart disease or radiation (x-ray) therapy to the chest area. Tell your doctor and pharmacist if you are taking or have ever received certain cancer chemotherapy medications such as daunorubicin (Cerubidine), doxorubicin (Doxil), epirubicin (Ellence), or idarubicin (Idamycin), or if you have ever been treated with mitoxantrone in the past. The risk of heart damage may depend on the total amount of mitoxantrone given to a person over a lifetime, so your doctor will probably limit the total number of doses you receive if you are using this medication for MS. If you experience any of the following symptoms, call your doctor immediately: difficulty breathing, chest pain, swelling of the legs or ankles, or irregular or fast heartbeat.

Mitoxantrone may increase your risk for developing leukemia (cancer of the white blood cells), especially when it is given in high doses or together with certain other chemotherapy medications.

Talk to your doctor about the risks of using mitoxantrone injection.

Why is this medication prescribed?

Mitoxantrone injection is used to adults with various forms of multiple sclerosis (MS; a disease in which the nerves do not function properly and people may experience weakness, numbness, loss of muscle coordination, and problems with vision, speech, and bladder control) including the following:

- relapsing-remitting forms (course of disease where symptoms flare up from time to time), or
- progressive relapsing (course of disease with occasional relapses), or
- secondary progressive forms (course of disease where relapses occur more often).

Mitoxantrone injection is also used together with steroid medications to relieve pain in people with advanced prostate cancer who did not respond to other medications. Mitoxantrone injection is also used with other medications to treat certain types of leukemia. Mitoxantrone injection is in a class of medications called anthracenediones. Mitoxantrone treats MS by stopping certain cells of the immune system from reaching the brain and spinal cord and causing damage. Mitoxantrone treats cancer by stopping the growth and spread of cancer cells.

How should this medicine be used?

Mitoxantrone injection comes as a liquid to be given intravenously (into a vein) by a doctor or nurse in a hospital or clinic. When mitoxantrone injection is used to treat MS, it is usually given once every 3 months for about 2 to 3 years (for a total of 8 to 12 doses). When mitoxantrone injection is used to treat prostate cancer, it is usually given once every 21 days. When mitoxantrone injection is used to treat leukemia, you will continue to receive this medication based on your condition and how you respond to the treatment.

If you are using mitoxantrone injection for MS, you should know that it controls MS but does not cure it. Continue to receive treatments even if you feel well. Talk to your doctor if you no longer want to receive treatment with mitoxantrone injection.

If you are using mitoxantrone injection for MS, ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

Mitoxantrone injection is also sometimes used to treat non-Hodgkin's lymphoma (NHL; cancer that begins in a type of white blood cell that normally fights infection). Talk to your doctor about the risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before using mitoxantrone injection,

- tell your doctor and pharmacist if you are allergic to mitoxantrone injection, any other medications, sulfites, or any of the other ingredients in mitoxantrone injection. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had any blood-clotting problems, anemia (decreased amount of red blood cells in the blood), or liver disease.
- tell your doctor if you are pregnant or plan to become pregnant. You should not become pregnant while you are using mitoxantrone injection. Talk to your doctor about effective birth control methods that you can use during your treatment. If you become pregnant while using mitoxantrone injection, call your doctor immediately. Mitoxantrone injection may harm the fetus. If you are using mitoxantrone injection to treat MS, even if you are using birth control, your doctor should give you a pregnancy test before each treatment. You must have a negative pregnancy test before the start of each treatment.
- tell your doctor if you are breastfeeding. Do not breastfeed while you are using mitoxantrone injection.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are using mitoxantrone injection.
- you should know that mitoxantrone injection is dark blue in color and may cause the white parts of your eyes to have a slight blue color for a few days after you receive each dose. It may also change the color of your urine to a blue-green color for about 24 hours after you receive a dose.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Call your doctor right away if you are unable to keep an appointment to receive a dose of mitoxantrone injection.

What side effects can this medication cause?

Mitoxantrone injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- vomiting
- diarrhea
- constipation
- heartburn
- loss of appetite

- sores on the mouth and tongue
- runny or stuffed nose
- thinning or loss of hair
- changes in the area around or under fingernails and toenails
- missed or irregular menstrual periods
- extreme tiredness
- weakness
- headache
- back pain

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- unusual bleeding or bruising
- small red or purple dots on the skin
- hives
- itching
- rash
- difficulty swallowing
- shortness of breath
- fainting
- dizziness
- pale skin
- yellowing of the skin or eyes
- seizures
- redness, pain, swelling, burning, or blue discoloration at the site where the injection was given

Mitoxantrone injection may cause other side effects. Call your doctor if you have any unusual problems while receiving this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed,

had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to mitoxantrone injection.

Ask your pharmacist any questions you have about mitoxantrone injection.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Novantrone[®] ¶

Other names

- DHAD

¶ - This branded product is no longer on the market. Generic alternatives may be available.

Last Revised - 10/15/2019

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Page last updated: 25 March 2022