

MEDICATION GUIDE
mitoXANTRONE (mito-xan-trone)
for injection concentrate

Read this Medication Guide before you start receiving mitoXANTRONE and each time you receive mitoXANTRONE. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information I should know about mitoXANTRONE?

MitoXANTRONE can cause serious side effects, including:

- **decrease in the ability of your bone marrow to make blood cells (myelosuppression).** Your doctor may do blood tests during treatment with mitoXANTRONE to check your blood cell counts. The symptoms of myelosuppression can include:
 - feeling tired
 - increased infections
 - bruising and bleeding easily
- **heart problems (congestive heart failure) that may lead to death even in people who have never had heart problems before.** Heart failure can happen while you receive mitoXANTRONE, or months to years after you stop receiving mitoXANTRONE. Your risk of heart failure increases the more mitoXANTRONE you receive.

Call your doctor or get medical help right away if you have any of these problems during or after treatment with mitoXANTRONE:

- shortness of breath
- swelling of your ankles or feet
- sudden weight gain
- fast heartbeat or pounding in your chest

Before receiving mitoXANTRONE for the first time, you should have the following tests done:

- physical examination
- a test to check your heart's electrical activity (electrocardiogram)
- a test to check your heart's ability to pump blood

If you receive mitoXANTRONE to treat Multiple Sclerosis (MS), your doctor should also do the tests above:

- before you receive each mitoXANTRONE dose
- yearly after you stop receiving mitoXANTRONE treatment
- **acute myeloid leukemia (AML).** Receiving mitoXANTRONE increases your risk of AML. AML is a cancer of the blood-forming cells of your bone marrow.

Symptoms of AML can include:

- feeling unusually tired and weak
- increased infections
- bruising and bleeding easily
- fever
- pain in your bones
- trouble breathing
- unexplained weight loss
- night sweats

- **skin problems at your injection site. If mitoXANTRONE leaks out of your vein, skin problems can happen that may lead to serious skin damage (necrosis). Necrosis may need to be repaired surgically.** Tell your doctor right away if you have any of the following problems at your injection site:

- redness
- swelling
- pain
- burning
- skin turns a bluish color

What is mitoXANTRONE?

MitoXANTRONE is a prescription medicine used alone or with other medicines to treat people with:

- secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis (MS)
- pain related to advanced hormone-refractory prostate cancer
- acute nonlymphocytic leukemia (ANLL)

MitoXANTRONE is not for people with primary progressive MS.

It is not known if mitroXANTRONE is safe and effective in children.

Who should not receive mitoXANTRONE?

Do not receive mitoXANTRONE if you are allergic to mitoXANTRONE or any of the ingredients in mitoXATRONE. See the end of this Medication Guide for a complete list of ingredients in mitoXATRONE.

What should I tell my doctor before receiving mitoXANTRONE?

Before you receive mitoXANTRONE, tell your doctor if you have:

- received mitoXANTRONE in the past
- heart problems
- liver problems
- kidney problems
- low blood cell counts
- an infection
- had radiation treatment in your chest area
- any other medical conditions
- **are pregnant or plan to become pregnant.** MitoXANTRONE may harm your unborn baby. Women who are able to become pregnant should use effective birth control (contraception) while using mitoXANTRONE and should have a

pregnancy test, with known results, before receiving each dose of mitoXANTRONE. Talk to your doctor about using effective birth control while you receive mitoXANTRONE.

- **are breastfeeding or plan to breastfeed.** MitoXANTRONE can pass into your breast milk and may harm your baby. Talk to your doctor about the best way to feed your baby if you receive mitoXANTRONE. Do not breastfeed while receiving mitoXANTRONE.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Using mitoXANTRONE with certain other medicines may cause serious side effects.

Especially tell your doctor if you take or have taken:

- medicines for cancer treatment called anthracyclines or anthracenediones
- medicines that may affect your heart

Ask your doctor or pharmacist for a list of these medicines if you are not sure if you take or have taken any of these medicines.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I receive mitoXANTRONE?

- MitoXANTRONE is given by slow infusion through a needle placed in a vein (intravenous infusion) in your arm.
- Your doctor will tell you how often you will receive mitoXANTRONE.
- If you receive mitoXANTRONE to treat MS, your doctor should check how well your heart is working before each mitoXANTRONE dose. Talk to your doctor if you have not had your heart tests done before your mitoXANTRONE dose.
- Your doctor will do blood tests during your treatment with mitoXANTRONE to check your blood cell counts.

- If you are a woman of childbearing age taking mitoXANTRONE to treat MS, your doctor should do a pregnancy test before each mitoXANTRONE dose, even if you are using birth control.
- If you receive mitoXANTRONE to treat MS, there is a limit to the total amount of mitoXANTRONE you can receive during your lifetime. There is a higher risk of heart failure with increasing total lifetime doses of mitoXANTRONE.

What are the possible side effects of mitoXANTRONE?

MitoXANTRONE may cause serious side effects, including:

- See “**What is the most important information I should know about mitoXANTRONE?**”

The most common side effects of mitoXANTRONE include:

- blue-green colored urine for about 24 hours after receiving mitoXANTRONE. This color change is harmless.
- bluish coloring of the whites of your eyes for about 24 hours after receiving mitoXANTRONE. This color change is harmless.
- nausea
- constipation
- diarrhea
- stomach pain
- hair loss
- fever and chills due to infections
- cough and sore throat due to upper respiratory tract infection
- mouth sores due to mouth infection
- loss of your menstrual period

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of mitoXANTRONE. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of mitoXANTRONE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about mitoXANTRONE. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about mitoXANTRONE that is written for health professionals.

For more information, call 1-877-447-3243.

What are the ingredients in mitoXANTRONE?

Active ingredient: mitoXANTRONE hydrochloride

Inactive ingredients: sodium chloride, sodium acetate, and acetic acid

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured for: EMD Serono, Inc. Rockland, MA 02370 USA

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