

NOVANTRONE® (noe-van-trone) mitoXANTRONE for injection concentrate

For Treating Multiple Sclerosis

Read this information carefully before you start taking NOVANTRONE® for multiple sclerosis (MS). This information does not take the place of talking with your doctor. Your doctor can tell you more about NOVANTRONE® and answer any questions you have about this treatment. NOVANTRONE® is used for other conditions besides MS. This leaflet has information about using NOVANTRONE® specifically for MS.

What is the most important information I should know about NOVANTRONE®?

- NOVANTRONE® can reduce relapses and disability for patients with worsening forms of MS.
- NOVANTRONE® may damage your heart at any time during therapy or months to years after therapy ends. Heart damage caused by NOVANTRONE® can be serious and may cause death. Your doctor will perform certain tests to see that your heart is working normally before you start to take NOVANTRONE®. Your doctor will repeat these heart tests before you receive each additional dose and every year after stopping NOVANTRONE®. Your doctor will also perform these tests if you have any symptoms of heart problems. Because the risk to your heart may depend on the total amount of NOVANTRONE® given, your doctor will limit the number of doses you get. Most patients will reach this limit after about 8 to 12 doses given over 2 to 3 years. After you have reached your limit, you should not receive any additional NOVANTRONE®. You and your doctor should both keep track of how much NOVANTRONE® you get. (See the sections “**What diagnostic tests will be performed?**” and “**What are the possible side effects of NOVANTRONE®?**”)
- MS and cancer patients treated with NOVANTRONE® have an increased risk of developing leukemia. Your doctor should perform blood tests before, during and every year after stopping treatment.
- NOVANTRONE® can increase your chance of getting an infection. If you begin to have any signs of infection, such as fever, chills, sore throat, cough, pain with urinating, or urinating more often, call your doctor right away. If you have such an infection, it can usually be treated by taking antibiotics.

What is NOVANTRONE®?

NOVANTRONE® is a medicine to treat MS patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting MS. It is not for treating primary progressive MS. Patients treated with NOVANTRONE® may have fewer relapses and keep their mobility longer.

Who should not take NOVANTRONE®?

Women who are pregnant, are trying to become pregnant, or are breastfeeding should not take NOVANTRONE® because it may harm the baby. You should use birth control while taking NOVANTRONE® to avoid becoming pregnant. Your doctor should also give you a pregnancy test before each dose, and you should know the results of this test before you get each dose of NOVANTRONE®. If you plan on getting pregnant, talk with your doctor about stopping the NOVANTRONE® treatments. If you do become pregnant, contact your doctor right away.

You should not take NOVANTRONE® if your doctor finds you have a low number of white blood cells (leukocytes).

You should not take NOVANTRONE® if your doctor finds your heart's ability to pump blood is decreased.

If you are allergic to NOVANTRONE®, you should not take it. The active ingredient is mitoxantrone. Ask your doctor about the inactive ingredients.

Your doctor needs to know the following information about you to help decide if NOVANTRONE® is right for you. Tell your doctor if you have now or had in the past:

- heart disease
- treatment with NOVANTRONE®
- cancer chemotherapy treatment
- radiation treatment to the chest area
- blood-clotting problems
- anemia or low red blood cell counts
- low white blood cell counts
- unusual or unexpected bleeding
- infections
- liver disease or problems
- any known allergies or sensitivities

Also tell your doctor if you take other medicines, including nonprescription medicines and nutritional supplements.

How do I take NOVANTRONE®?

NOVANTRONE® is given through a needle placed in a vein in your arm. The dose takes about 5 to 15 minutes to deliver. NOVANTRONE® treatment is usually given once every 3 months for about 2 to 3 years (8 to 12 doses). However, this may differ for different patients.

What diagnostic tests will be performed?

You will need to have regular testing of your heart and blood to help avoid serious side effects.

Before each dose of NOVANTRONE®, your doctor will take blood samples to check your blood counts and liver function. Your doctor may also take a blood sample if you begin to have signs of an infection. If you are a woman who is capable of becoming pregnant, even if you are using birth control, you must have a pregnancy test before each NOVANTRONE® dose, and you should know the results before you receive each NOVANTRONE® dose.

To measure possible changes to the heart, you should have regular electrocardiograms (ECGs) and you should have regular testing of your heart's ability to pump blood. Measuring your heart's ability to pump blood requires taking pictures of your heart using a simple, painless test such as an echocardiogram. Your heart should be tested before each dose of NOVANTRONE®, or if you show signs of heart problems.

You and your doctor should carefully track the total amount of NOVANTRONE® you get. Your doctor may stop NOVANTRONE® if your tests show that your heart's ability to pump blood has decreased. If you change doctors, make sure your new doctor knows how much NOVANTRONE® you have taken.

What should I avoid while taking NOVANTRONE®?

- Women should not become pregnant or breastfeed while taking NOVANTRONE® because it may harm the baby. Talk with your doctor about effective birth control. Tell your doctor if you become pregnant.
- Talk with your doctor about any medicines you currently take and any medicines you plan to start or stop taking. These include prescription and non-prescription medicines and nutritional supplements. Some medicines may affect how NOVANTRONE® works.

What are the possible side effects of NOVANTRONE®?

Most side effects of NOVANTRONE® are not severe and can normally be treated by your doctor. The most common side effects of NOVANTRONE® in patients with MS are nausea, hair thinning, loss of menstrual periods, bladder infections, and mouth sores. The nausea is usually mild and generally lasts for less than 24 hours. A small number of patients treated with NOVANTRONE® develop heart problems during treatment or after treatment has stopped. Tell your doctor if you have trouble breathing, swelling of your legs or ankles, or uneven or fast heartbeat. These problems generally happen in people who get a total lifetime dose of more than 12 doses (usually more than 140 mg/m²) of NOVANTRONE®, but can also occur at lower lifetime doses.

NOVANTRONE® may cause your white blood cell count to go down, which increases your chance of getting an infection. This risk is greatest within one month after each dose. In addition, NOVANTRONE® may cause your platelet count to go down, which increases your chance of bleeding. Call your doctor right away if you begin to have fever, chills, sore throat, cough, pain with urination, urination more often, or if you notice any unusual bleeding or bruising.

NOVANTRONE® is dark blue in color, so it may turn your urine a blue-green color for a few days after each dose. The white part of your eyes may also have a slight blue color.

Other side effects may occur. Be sure to tell your doctor about any side effects whether or not they are listed here.

General advice about prescription medicines

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. If you have any concerns about NOVANTRONE®, ask your doctor. Your doctor can give you information about NOVANTRONE® that was written for healthcare professionals. For more information, call MS LifeLines toll free at 1-877-447-3243.

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

NOVANTRONE® is a registered trademark of EMD Serono, Inc.
©2009 EMD Serono, Inc. All rights reserved. 09-22161 09/09
Printed in the USA Issued Date 09/2009

