

Mitoxantrone

# Medication guide for patients

Essential information on risk minimization for patients starting a therapy with **mitoxantrone** (active ingredient: mitoxantrone).

**Mitoxantrone** 2 mg/ml concentrate for solution for infusion is indicated for treatment of patients with highly active relapsing multiple sclerosis associated with rapidly evolving disability where no alternative therapeutic options exist.

# Possible side effects of mitoxantrone

Like all medications, mitoxantrone causes side effects but not every patient gets them. The most serious side effects are:

## 1. Heart failure

Mitoxantrone can damage your heart and cause your heart function to worsen culminating in its severest form, heart failure.

### *What is heart failure?*

Mitoxantrone can damage your heart and reduce the 'ejection fraction' of your heart. This refers to the amount of blood ejected by the left chamber of the heart with each heartbeat. It is usually given as a percentage. A normal ejection fraction is around 50-65%, as some blood remains in the heart after each heartbeat. A lower ejection fraction does not necessarily cause clinical symptoms.

In its severest form, heart failure, sometimes also called congestive heart failure (CHF), clinical symptoms can occur. Symptoms occur because the heart does not have enough strength to pump the blood around the whole body properly. As a result, fluid can collect in the feet and legs. If nothing is done to prevent the fluid accumulation, it can increase and reach your stomach and under your lungs. This reduces the lungs ability to enlarge and makes you short of breath.

These side effects are more likely if you receive higher doses of mitoxantrone or if

- you have previously received mitoxantrone.
- you have already had heart problems before taking mitoxantrone.
- you have had radiotherapy in the chest area.
- you are already taking other medications that affect your heart.
- you have previously received treatments with anthracyclines or anthracendiones, such as daunorubicin or doxorubicin.

This medication guide for patients describes some of the serious risks (cardiovascular and haematological risk) associated with administration of mitoxantrone. It aims to inform patients of these risks and includes important recommendations on how these risks can be reduced.

Your doctor has prescribed you a medication to treat your multiple sclerosis (MS) called mitoxantrone. The treatment must not be initiated in patients who have been previously treated with mitoxantrone.

If you read this guide carefully, you will learn more about mitoxantrone and some of its potential side effects.

This guide is not intended to replace conversations with your doctor or other healthcare staff in the treatment of your MS. You should also read it together with the package insert for mitoxantrone.

Your doctor should also provide you with a patient alert card which contains essential information on this medicine, and you should show this to all doctors involved in your treatment, not just your neurologist.

## ***What will my doctor do to minimise the risk of developing heart failure?***

Your doctor will check your heart function (ejection fraction) before starting treatment with mitoxantrone, before each subsequent dose and annually for up to 5 years after ending treatment.

Your doctor will have to adjust your treatment or stop the mitoxantrone temporarily or permanently if your heart function worsens.

The maximum cumulative lifetime dose of mitoxantrone must not exceed 72 mg/m<sup>2</sup> body surface area. **Therefore, it is important to perform tests both during the treatment and for up to 5 years after the last dose of mitoxantrone (even if you are feeling well).**

## ***What can you do to minimise the risk of developing heart failure?***

**Tell your doctor immediately if you get any of the below signs or symptoms during or after treatment with mitoxantrone**

### **What are the signs and symptoms of heart failure?**

- shortness of breath
- fluid accumulation (swelling) in the ankles and legs
- changes in heartbeat rate (fast or slow)
- fatigue
- decreased ability for physical activity

These may occur either during or even months or years after treatment with mitoxantrone.

## ***What will happen if I develop heart failure?***

Heart failure is incurable currently, but there are treatments available to control the symptoms, especially if they are recognised early. Your doctor will have to adjust your treatment or stop the mitoxantrone temporarily or permanently if your heart function worsens.

**Therefore, it is essential that you recognise any signs or symptoms and tell your doctor immediately.**

## **2. Acute myeloid leukaemia (AML) and myelodysplastic syndrome (MDS)**

A group of cancer medications (topoisomerase II inhibitors), to which mitoxantrone belongs, can cause the following conditions when taken alone or in combination with other cancer medications and/or radiotherapy:

- AML
- MDS

### ***What are AML and MDS?***

AML is a cancer of the white blood cells characterised by the rapid growth of abnormal white blood cells which accumulate in the bone marrow and disrupt the production of normal blood cells. The symptoms of AML are caused as a consequence of the normal bone marrow being replaced by leukaemic cells, and this leads to a decrease in the number of red and white blood cells and platelets.

MDS is a disease of the bone marrow that leads to immature and abnormally formed white blood cells and low cell counts, especially of red blood cells but also of white blood cells and platelets. The low cell counts can cause symptoms, but it may also be the case that you have no symptoms at all. MDS can develop into AML.

## ***What will my doctor do to minimise the risk of developing AML and MDS?***

Before treatment with mitoxantrone and during the treatment, your doctor will perform blood tests to determine your blood cell counts.

**It is therefore very important to perform tests before and during the therapy with mitoxantrone (even if you are feeling well).**

## ***What can you do to minimize the risk of developing AML and MDS?***

Tell your doctor immediately if you get any of the below signs or symptoms during or after treatment with mitoxantrone

### ***What are the signs and symptoms of acute myeloid leukaemia (AML) and myelodysplastic syndrome (MDS)?***

- Fever or infections (signs of a low white blood cell count)
- If your skin becomes pale and you feel weak or suffer sudden respiratory distress (possible signs of a low red blood cell count)
- Unusual blue spots or bleeding, such as coughing up blood, blood in vomit or in urine or black stool (possible signs of low platelet count)

These can still occur months or even years after the completion of your treatment with mitoxantrone.

## ***What will happen I develop AML or MDS?***

If it is recognized early, AML and MDS are treatable. If you develop AML or MDS, you and your doctor will decide which treatment is best for you.

**Therefore, it is essential that you recognise any signs or symptoms and tell your doctor immediately.**

### Reporting side effects:

If you notice side effects, contact your doctor or pharmacist. You can also report side effects directly to the Health Products Regulatory Authority (HPRA) at: website: [www.hpra.ie](http://www.hpra.ie)

Any suspected adverse reactions may also be reported to Pfizer Medical Information on 1800 633 363.

By reporting side effects, you can help provide more information on the safety of this medicine.

Further information can be found in the Package Leaflet of mitoxantrone and on the website: [www.medicines.ie](http://www.medicines.ie)

# Mitoxantrone