Mitoxantrone

Checklist for the prescribing physician

Essential information for risk minimization in the treatment of patients with highly active relapsing multiple sclerosis associated with rapidly evolving disability where no alternative therapeutic options exist.

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.

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This checklist was developed as part of a Risk Management Plan (RMP) for prescribing physicians and medical staff working in the care of patients being treated with mitoxantrone. Mitoxantrone is indicated for the treatment of patients with highly active relapsing multiple sclerosis (MS) associated with rapidly developing disability for which no alternative treatment options exist.

Whilst the risks of cardiotoxicity and leukaemia are associated with all mitoxantrone's licensed indications, they are considered key to the benefit-risk balance for use in MS patients are therefore additional risk minimisation measures in the form of educational materials for prescribers and patients have been developed.

These educational materials are developed and provided to inform healthcare professionals and patients of the risks of cardiotoxicity and leukaemia and related monitoring requirements during and after treatment for multiple sclerosis, with the aim to facilitate treatment initiation decision-making and ensure the risks are adequately minimized.

Please note that this guide does not deal with all adverse reactions that may occur in association with administration of mitoxantrone. A full description of the potential adverse reactions can be found in the Summary of Product Characteristics.

Further information can be found in the Summary of Product Characteristics for mitoxantrone and on the website: www.medicines.ie

Reporting of Adverse Events

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance: www.hpra.ie

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

Before the initial treatment

This treatment must not be initiated in patients who have been previously treated with mitoxantrone.

Action	Details
Analysis of medical history	Patient screening for increased risk of cardiac and haematological toxicity ☐ Underlying risk factors for cardiotoxicity (e.g. active or latent cardiovascular diseases, prior therapy with other anthracyclines or anthracendiones or other cardiotoxic medications, radiotherapy of the mediastinal/pericardial area) ☐ Underlying risk factors for haematological toxicity
Screening tests for baseline values	☐ Test for left-ventricular ejection fraction (LVEF) by echocardiogram or gated equilibrium radionuclide ventriculography (ERNV) [Normally, mitoxantrone should not be administered to MS patients with an LVEF of <50% or a clinically significant reduction in LVEF.] ☐ A complete blood count, including platelets, must be performed before administering the initial dose of mitoxantrone
Patient Counselling	☐ The patient has been explained the risks and understands them, including cardiotoxicity (i.e. worsening of LVEF, congestive heart failure [CHF]) and haematotoxicity (i.e. treatment- related acute myeloid leukaemia [AML] and myelodysplastic syndrome [MDS]) associated with the administration of mitoxantrone for the treatment of MS and the measures for risk minimisation (e.g. looking out for symptoms, carrying a patient alert card and the need to undergo regular tests for up to 5 years after the end of treatment).

During the treatment and for up to 5 years after the last treatment

Time	Action	Details
	Cumulative lifetime dose	☐ Patients with multiple sclerosis should normally not receive a cumulative lifetime dose of mitoxantrone of more than 72 mg/m².
	Monitoring	☐ Testing for LVEF by echocardiogram or ERNV before each subsequent dose and annually for up to 5 years after ending therapy. [Normally, mitoxantrone should not be administered to MS patients with an LVEF of <50% or a clinically significant reduction in LVEF.] ☐ Complete blood count including platelets 10 days after administration of the initial dose, before each subsequent infusion and at signs and symptoms of an infection.

Name of the patient: _____

Date of birth of the patient: _____

Name of the prescribing physician: _____

Start date of mitoxantrone therapy: _____

End date of mitoxantrone therapy: _____

Cumulative lifetime dose received: _____ mg/m²