

Mitoxantrone



When requesting mitoxantrone the individual requiring treatment must be diagnosed with the following FDA-approved indications or approved compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indications¹

- Mitoxantrone is indicated for reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing multiple sclerosis (i.e., patients whose neurologic status is significantly abnormal between relapses). Mitoxantrone is not indicated in the treatment of individuals with primary progressive multiple sclerosis.
- Mitoxantrone in combination with corticosteroids is indicated as initial chemotherapy for the treatment of individuals with pain-related to advanced hormone-refractory prostate cancer.
- Mitoxantrone in combination with other approved drug(s) is indicated in the initial therapy of acute nonlymphocytic leukemia (ANLL) in adults. This category includes myelogenous, promyelocytic, monocytic, and erythroid acute leukemias.

Approved Off-label Compendial uses^{2,3}

- Acute lymphocytic leukemia²
- Autologous bone marrow transplantation²
- Breast cancer²
- Head and neck cancer²
- Hodgkin's lymphoma³
- Liver cancer²
- Malignant lymphoma, indolent²
- Non-Hodgkin's lymphoma³
- Ovarian cancer²
- Pleural effusion²
- Solid tumor, malignant²

Coverage Guidelines

For All Indications:

- Cardiac signs and symptoms must be assessed by history, physical examination, and ECG prior to start of mitoxantrone therapy¹
- Must have baseline quantitative evaluation of left ventricular ejection fraction (LVEF)¹

For Multiple Sclerosis (MS):

- Has one of the following forms of MS: secondary progressive, progressive relapsing, or relapsing-remitting MS¹
- Has a baseline LVEF above the lower limit of normal¹

- Has not experienced a drop in LVEF to below the lower limit of normal or a clinically significant reduction in LVEF during mitoxantrone injection¹
- Has not have received a cumulative lifetime mitoxantrone dose greater than 140mg/m²¹
- Prior to initiating mitoxantrone therapy, baseline neutrophil count is/was 1,500 cells/mm³ or greater¹

For Prostate Cancer:

- Has hormone-refractory (castration-recurrent) metastatic disease^{1,3}
- Use mitoxantrone in combination with corticosteroids^{1,3}
- Prior to initiating mitoxantrone therapy, baseline neutrophil count is/was 1,500 cells/mm³ or greater¹

For Acute Nonlymphocytic Leukemia (ANLL) including myelogenous, promyelocytic, monocytic, and erythroid acute leukemias:

- Use mitoxantrone in combination with other approved drug(s)¹

For Non-Hodgkin's Lymphoma (NHL):

- Has one of the following NHL subtypes: AIDS-related B-cell lymphoma, diffuse large B-cell lymphoma, follicular lymphoma, gastric MALT lymphoma, mantle cell lymphoma, nongastric MALT lymphoma, primary cutaneous B-cell lymphoma, splenic marginal zone lymphoma, or T-cell prolymphocytic leukemia³
- Has refractory or progressive disease except for T-cell prolymphocytic leukemia³
- Use mitoxantrone in combination with other chemotherapy regimens³
- Prior to initiating mitoxantrone therapy, baseline neutrophil count is/was 1,500 cells/mm³ or greater¹

For Acute Lymphocytic Leukemia:

- Use mitoxantrone in combination with other chemotherapy regimens²

For Malignant Lymphoma, Indolent:

- Use mitoxantrone in combination with other chemotherapy regimens²
- Prior to initiating mitoxantrone therapy, baseline neutrophil count is/was 1,500 cells/mm³ or greater¹

For Head and Neck Cancer:

- Use mitoxantrone as a single agent²
- Prior to initiating mitoxantrone therapy, baseline neutrophil count is/was 1,500 cells/mm³ or greater¹

For Solid Tumor, Malignant:

- Member is a pediatric²
- Prior to initiating mitoxantrone therapy, baseline neutrophil count is/was 1,500 cells/mm³ or greater¹
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For Hodgkin's Lymphoma (HL):

- Use as a second-line or subsequent therapy OR use as a primary therapy for classical HL

- Use mitoxantrone in combination with other chemotherapy regimens³
- Prior to initiating mitoxantrone therapy, baseline neutrophil count is/was 1,500 cells/mm³ or greater¹

For breast cancer, liver cancer, ovarian cancer, pleural effusion, and autologous bone marrow transplantation:

- Prior to initiating mitoxantrone therapy, baseline neutrophil count is/was 1,500 cells/mm³ or greater¹

Additional Information for Prescribers¹

- Frequent peripheral blood cell counts recommended to monitor for the occurrence of bone marrow suppression and/or primary neutropenia
- Congestive heart failure (CHF), potentially fatal, may occur either during therapy or months to years after termination of therapy. Presence of history of cardiovascular disease, radiotherapy to the mediastinal/pericardial area, previous therapy with other anthracyclines or anthracenediones, or use of other cardiotoxic drugs may increase this risk.
- Multiple sclerosis patients should be assessed for cardiac signs and symptoms prior to each dose
- Multiple sclerosis patients should undergo reevaluation of LVEF prior to each dose, and annual LVEF evaluations after stopping mitoxantrone, with the same methodology used to assess baseline LVEF
- Mitoxantrone injection increases the risk of developing secondary acute myeloid leukemia

References

1. Novantrone prescribing information. Irvine, CA: Teva Parenteral Medicines, Inc. May 2012. Accessed February 02, 2017.
2. Klasco RK (Ed): DRUGDEX® System. Thomson Micromedex, Greenwood Village, CO. Accessed February 02, 2017. <https://www.micromedexsolutions.com>.
3. National Comprehensive Cancer Network Drugs & Biologics Compendium (NCCN Compendium®). Assessed February 02, 2017. https://www.nccn.org/professionals/drug_compendium/MatrixGenerator/Matrix.aspx?AID=21. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™). ©2017 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.

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