

## Patient Treatment Information

# Mitoxantrone + Prednisone

---

Your chemotherapy treatment is called mitoxantrone (mye-toe-ZAN-trone) or Novantrone® (no-VAN-trone) + prednisone (pred-nee-zone). It is commonly used to treat prostate cancer and has also been used to treat other diseases. Mitoxantrone prevents cancer cells from dividing and growing, and can eventually cause the cancer cells to shrink and die. Prednisone is a corticosteroid.

### What Do I Need to Know Before Starting Treatment?

Be sure to tell your healthcare provider about any prescription or over-the-counter products you are taking, including dietary supplements, vitamins, herbal medicines and homeopathic remedies.

Use an effective birth control method while you are being treated. Chemotherapy drugs can cause harm to a fetus, so be sure to tell your healthcare provider right away if you or your partner become pregnant.

Avoid breastfeeding during treatment. It is not known if chemotherapy drugs pass into breast milk.

Some chemotherapy drugs can cause sterility. Talk with your healthcare provider about your options if you want to have children in the future.

Do not get any immunizations or vaccinations while you are being treated without the approval of your healthcare provider.

### What Do I Need to Know Before Starting Mitoxantrone + Prednisone?

Mitoxantrone can cause heart problems during treatment or months or years after your treatment ends. Your risk of heart damage increases as the total dose of mitoxantrone or similar chemotherapy medicines you take increases. Tell your healthcare provider if you have heart disease or if you have been treated with chemotherapy or radiation therapy to the chest. Call your healthcare provider immediately if you have back pain, flushing or chest tightness.

Mitoxantrone can cause irritation if it accidentally leaks out of the vein. Tell your healthcare provider right away if you feel pain, burning or swelling around the injection site during your treatment.

Mitoxantrone can cause tumor lysis syndrome (TLS), which occurs when chemotherapy kills large numbers of cancer cells and causes abnormal changes in blood chemistry. In rare cases, TLS can cause kidney failure that requires dialysis. Your healthcare provider will check your blood for TLS.

Mitoxantrone can cause an allergic reaction. In rare cases, the reaction can be severe and life-threatening. Tell your healthcare provider immediately if you have itching, dizziness or fainting, trouble breathing or swelling of the lips, throat or tongue.

Mitoxantrone can cause urine to turn green or blue for one to two days after treatment. The white part of the eyes can also turn blue. The green or blue color is caused by the medicine and is not harmful.

In rare cases, mitoxantrone can cause secondary cancer or leukemia several years after treatment.

Prednisone can reduce the stomach's protective layer, making it more prone to irritation by stomach acid. In rare cases, this can lead to bleeding ulcers. Tell your healthcare provider if you have indigestion or other stomach problems. Your healthcare provider may give you medicine to help relieve these symptoms.

Prednisone may cause your blood-sugar level to rise, especially if you have diabetes mellitus. During treatment you may have regular blood or urine tests to check your blood sugar. Tell your healthcare provider if you get very thirsty or if you are urinating more than usual.

Prednisone may increase your blood pressure. Tell your healthcare provider immediately if you have headaches, visual disturbances, confusion or sleepiness.

Prednisone may increase your risk of infection and make the signs of infection, such as fever, difficult to detect. Tell your healthcare provider immediately if you develop any signs of infection (see “What Are The Possible Side Effects?”).

Your treatment can interact with other substances, including:

- Non-steroidal anti-inflammatory drugs, such as aspirin, ibuprofen or naproxen
- Warfarin (Coumadin®)
- Phenytoin (Dilantin®, phenobarbital (Luminal®) or carbamazepine (Tegretol®)
- Rifampin or rifabutin
- Digoxin (Lanoxin®)
- Furosemide (Lasix®)
- Drugs used to treat diabetes, including insulin
- Drugs used to treat thyroid conditions
- Ketoconazole (Nizoral®)
- Amiodarone (Cordarone®)

Please note this list is a summary and does not contain all possible drug interactions. Contact your healthcare provider if you are taking any medications that can interact with your treatment.

**You should not take this treatment** if you are allergic to mitoxantrone, prednisone or any components of these drugs.

## How Is the Treatment Given?

Your healthcare provider will give you mitoxantrone by injection into a vein. The dose you receive will be based on your weight and height. Your healthcare provider will determine the number of treatments you receive.

You will take prednisone by mouth. To minimize stomach irritation, take prednisone with food and don't drink alcohol while taking prednisone. If you miss a dose, take the prednisone as soon as you remember, then contact your healthcare provider for advice on when to take the next dose.

Store the prednisone at room temperature away from children and pets. If you take too much of the prednisone, contact your healthcare provider, local poison control center or emergency room right away.

If you are given any medicine to take at home, do not share it with others. Sharing this medication with anyone else could be harmful.

## When Should I Call My Healthcare Provider?

Call your healthcare provider right away if you have any of the following symptoms:

- Shaking chills or fever of 100.5 degrees F or higher
- Unusual bleeding, easy bruising or pinpoint red spots on your skin
- Vomiting that is severe or lasts several hours
- Painful or frequent urination or blood in your urine
- Diarrhea that causes an additional four bowel movements a day, diarrhea that lasts more than one day, diarrhea at night or diarrhea with fever, cramps or bloody stools
- Irregular or rapid heart beat, chest pain, chest tightness or shortness of breath
- Dizziness or feeling lightheaded
- Inability to eat or weight loss

## What Are the Possible Side Effects?

All drugs can cause side effects, but every person reacts differently to each drug. The following chart lists the possible side effects that can occur with your treatment, how to recognize and minimize symptoms and possible treatments. The side effects are grouped by how often the side effect occurs: Common (occurs in more than 25 percent of patients), Less Common (occurs in 5 to 25 percent of patients) or Rare (occurs in less than 5 percent of patients).

Side Effect	How to Minimize Side Effect	Possible Treatments
<p><b>Risk of Infection (Common)</b></p> <ul style="list-style-type: none"> <li>• Fever and chills</li> <li>• Painful urination</li> <li>• Sore throat and cough</li> <li>• Nasal congestion</li> <li>• Swelling or redness of the skin at the site of a wound</li> </ul>	<ul style="list-style-type: none"> <li>• Wash your hands often.</li> <li>• Brush and floss your teeth daily.</li> <li>• Clean cuts right away with warm water, soap and antiseptic.</li> <li>• When your white blood cell count is low, stay away from crowds and people with colds or other illnesses.</li> </ul>	<ul style="list-style-type: none"> <li>• You may be given medicine to increase your white blood cell count.</li> <li>• You may be given an antibiotic to treat or prevent infection.</li> <li>• Your healthcare provider may decrease your chemotherapy dose or delay further chemotherapy.</li> </ul>
<p><b>Nausea/Vomiting (Common. Symptoms are generally mild to moderate.)</b></p> <ul style="list-style-type: none"> <li>• Feeling queasy or sick to your stomach</li> </ul>	<ul style="list-style-type: none"> <li>• Eat small, frequent meals and bland foods—such as bananas, rice, applesauce and toast.</li> <li>• Eat food cold or at room temperature so the smell of food will not bother you.</li> <li>• Avoid fried, spicy or fatty foods.</li> <li>• Eat and drink slowly.</li> <li>• Drink plenty of liquids during the day, but to avoid bloating, drink small amounts of liquid during meals.</li> </ul>	<ul style="list-style-type: none"> <li>• You will be given medicine to help reduce nausea and vomiting.</li> </ul>
<p><b>Mouth Sores and Pain (Less Common)</b></p> <ul style="list-style-type: none"> <li>• Pain, swelling or redness of the mouth, tongue and throat</li> <li>• “Coated tongue”</li> <li>• Difficulty talking, swallowing or eating</li> <li>• Bleeding ulcers and infection</li> </ul>	<ul style="list-style-type: none"> <li>• Bleeding ulcers and infection</li> <li>• Brush teeth two to four times a day using a soft bristle brush and fluoride toothpaste.</li> <li>• Use non-waxed dental floss daily.</li> <li>• Ask your healthcare provider to recommend a mouthwash that does not contain alcohol.</li> <li>• Sip water during the day and use sugar-free candy or gum to keep your mouth wet.</li> <li>• Eat food cold or at room temperature.</li> <li>• Eat soft or pureed food.</li> <li>• Avoid food that is acidic, spicy, salty, dry or rough, such as toast.</li> </ul>	<ul style="list-style-type: none"> <li>• You may be given medicine to help treat pain.</li> <li>• You may be given medicine to treat fungal or viral infections.</li> </ul>
<p><b>Alopecia or Hair Loss (Less Common. Does not usually cause complete hair loss.)</b></p> <ul style="list-style-type: none"> <li>• More than normal amount of hair loss in your brush, in the shower or on your pillow after sleeping</li> <li>• Loss of body hair</li> </ul>	<p>Alopecia cannot be prevented but here are tips to help with hair loss:</p> <ul style="list-style-type: none"> <li>• Use a soft hairbrush. Do not use brush rollers, color treat your hair or get a permanent.</li> <li>• Avoid daily hair washing, use a mild shampoo and avoid using a hairdryer, or use a low setting if you must use one.</li> <li>• Have your hair cut short; this will make it look fuller.</li> <li>• Your insurance might cover a wig. Ask your healthcare provider for a prescription for a "hair prosthesis". Your hair color and style can be better matched if you shop for a wig before losing a lot of hair.</li> <li>• Use sunscreen or wear a hat or scarf to protect your scalp from the sun.</li> </ul>	
<p><b>Diarrhea (Less Common. Symptoms are generally mild.)</b></p> <ul style="list-style-type: none"> <li>• Loose or watery stools several times a day</li> <li>• Abdominal cramping, gas and bloating</li> </ul>	<ul style="list-style-type: none"> <li>• Eat small, frequent meals and bland foods—such as bananas, rice, applesauce and toast.</li> <li>• Avoid caffeine; alcohol; raw fruits and vegetables; raw eggs; undercooked meats; spicy, fatty and greasy foods; milk and dairy products; foods that cause gas, such as beans and other legumes; high fiber and high-fat foods; foods left un-refrigerated for more than two hours (one hour for egg dishes and cream or mayonnaise-based foods); bulk laxatives; and stool softeners.</li> </ul>	<ul style="list-style-type: none"> <li>• Drink eight to ten glasses of clear liquids every day.</li> <li>• Your healthcare provider may prescribe medicine to help treat diarrhea.</li> </ul>
<p><b>Anorexia or Appetite Loss (Less Common. Symptoms are generally mild.)</b></p> <ul style="list-style-type: none"> <li>• Not having an appetite</li> <li>• Feeling too nauseated to eat</li> <li>• Metallic or medicinal taste</li> <li>• Change in taste causing dislike</li> </ul>	<ul style="list-style-type: none"> <li>• Try eating six to eight small meals or snacks each day instead of three larger meals.</li> <li>• Vary your diet and try new foods and recipes.</li> <li>• Take a walk before meals, when possible. This may make you feel hungrier.</li> <li>• Eat with friends or family. When eating alone, listen to the radio or watch TV.</li> </ul>	<ul style="list-style-type: none"> <li>• Cook dinners ahead of time and freeze them in small portions so that cooking smells are minimized.</li> <li>• Let others help with food, but ask that foods be prepared in small portions that can be frozen. And don't hesitate to let them know which foods to avoid.</li> </ul>

Side Effect	How to Minimize Side Effect	Possible Treatments
for certain foods		<ul style="list-style-type: none"> <li>• Add mild spices to change flavor.</li> <li>• It might be helpful to have a program, such as Meals on Wheels, deliver food to you.</li> </ul>
<b>Neuropathy (Less Common. Symptoms are generally mild.)</b> <ul style="list-style-type: none"> <li>• Numbness or tingling feeling in the hands or feet</li> <li>• Muscle cramps</li> <li>• Loss of balance</li> <li>• Difficulty buttoning buttons or picking up objects</li> <li>• Decreased awareness of heat or cold in fingertips and toes</li> <li>• Difficulty hearing</li> </ul>	<ul style="list-style-type: none"> <li>• Try to avoid the cold or extreme heat.</li> <li>• Wear mittens or gloves, socks and scarves.</li> <li>• If your fingers are numb, be careful with sharp objects.</li> <li>• Beware of hot coffee mugs, pots and pans and dishwasher—you may not feel the heat until you are burned.</li> <li>• If you feel unsteady, be careful on stairs and in the shower</li> </ul>	<ul style="list-style-type: none"> <li>• Your healthcare provider may decrease your chemotherapy dose or delay further chemotherapy.</li> </ul>
<b>Nail Changes (Less Common)</b> <ul style="list-style-type: none"> <li>• Darkening of the nails that usually grows out with the nail</li> <li>• Vertical or horizontal bands on the nails</li> </ul>	<ul style="list-style-type: none"> <li>• Trim nails often and keep them clean.</li> <li>• Wear gloves for cleaning and gardening to minimize damage and prevent infection.</li> <li>• Don't wear nail polish or false fingernails until the nails have grown out and returned to normal.</li> </ul>	<ul style="list-style-type: none"> <li>• You may be given an antibiotic if there is an infection in the nail bed.</li> </ul>
<b>Fluid Retention (Rare. Symptoms are generally mild.)</b> <ul style="list-style-type: none"> <li>• Swelling around the eyes, lower legs, ankles, feet or abdominal area</li> <li>• Sudden weight gain</li> </ul>	<ul style="list-style-type: none"> <li>• Check your weight regularly.</li> <li>• Try to avoid eating salty foods, as this can cause fluid retention.</li> </ul>	<ul style="list-style-type: none"> <li>• You may be given a diuretic (water pill) to reduce the amount of fluid in your body.</li> <li>• Your healthcare provider may decrease your chemotherapy dose or delay further chemotherapy.</li> </ul>
<b>Anemia (Rare)</b> <ul style="list-style-type: none"> <li>• Fatigue or weakness</li> <li>• Dizziness</li> <li>• Pale skin</li> <li>• Feeling out of breath</li> <li>• Feeling cold</li> </ul>	<ul style="list-style-type: none"> <li>• Plan rest periods throughout the day.</li> <li>• Organize daily activities so that you conserve your energy.</li> <li>• Try to eat a well balanced diet and drink plenty of fluids.</li> <li>• Stand up slowly to avoid getting dizzy.</li> </ul>	<ul style="list-style-type: none"> <li>• You may be given medicine to increase your red blood cell count.</li> <li>• Your healthcare provider may decrease your chemotherapy dose or delay further chemotherapy.</li> </ul>
<b>Bleeding (Rare)</b> <ul style="list-style-type: none"> <li>• Unusual bleeding or easy bruising</li> <li>• Black or tar-like stools</li> <li>• Blood in your urine</li> <li>• Pinpoint red spots on your skin</li> <li>• Bleeding gums or nosebleeds</li> </ul>	<ul style="list-style-type: none"> <li>• Avoid aspirin and aspirin-like drugs, such as ibuprofen.</li> <li>• Use caution with sharp objects, such as razors and nail cutters.</li> <li>• Avoid activities that can cause cuts, bumps and bruises.</li> </ul>	<ul style="list-style-type: none"> <li>• You may be given medicine to increase your platelet count.</li> <li>• Your healthcare provider may decrease your chemotherapy dose or delay further chemotherapy.</li> </ul>

## What Are the Other Possible Side Effects?

The following chart lists additional side effects found with the individual drugs in this treatment. It does not list all possible side effects. For more information, talk with your healthcare provider.

Common Side Effects	Less Common Side Effects	Rare Side Effects
<ul style="list-style-type: none"> <li>• Fatigue</li> <li>• Increased appetite</li> <li>• Nervousness, restlessness or insomnia</li> </ul>	<ul style="list-style-type: none"> <li>• Changes in taste</li> <li>• Abdominal pain</li> <li>• Cough or shortness of breath</li> <li>• Headache</li> <li>• Eye infections, glaucoma or cataracts</li> </ul>	<ul style="list-style-type: none"> <li>• Seizures</li> <li>• Mood swings, personality changes, hallucinations or severe depression</li> </ul>

## Notes

---

---

---

---

---

---

**Disclaimer.** The drug information presented is time-sensitive and current as of the date stated below. It is not a substitute for the expertise, skill, knowledge and judgment of healthcare practitioners. Additional, important information about this product is available from the manufacturer and other sources. ONMARK PROVIDES THIS DRUG INFORMATION ON AN "AS IS" BASIS. ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE DISCLAIMED.

**Limitation of Liability.** Onmark shall not be liable for any improper or incorrect use of the information described and contained herein and assumes no responsibility for anyone's use of the information. IN NO EVENT SHALL ONMARK BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OR SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE USE OF THIS INFORMATION, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

**This document is a complimentary service provided by Onmark for its members. [www.onmarkservices.com](http://www.onmarkservices.com)  
© 2007 Onmark, Inc. Onmark is a trademark of Oncology Therapeutics Network**

**December 2007**

**References:**

1. Tannock, et al. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer. NEJM 2004; 351:1502-1512
2. Petrylak, et al. Docetaxel and estramustine compared with mitoxantrone and prednisone for advanced refractory prostate cancer. NEJM 2004;351;1513-20