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Mitotane

pronounced as (mye' toe tane)

IMPORTANT WARNING:

Mitotane may cause a serious, life-threatening condition that can occur when not enough hormone (cortisol) is produced by the adrenal glands in your body. Mitotane must be taken under the supervision of a doctor who has experience in using medications to treat cancer. If you develop a severe infection, illness, or injury you should stop taking mitotane and call your doctor immediately.

Why is this medication prescribed?

Mitotane is used to treat cancer of the adrenal gland that can not be treated with surgery. Mitotane is in a class of medications called antineoplastic agents. It works by slowing growth or reducing the size of the tumor.

How should this medicine be used?

Mitotane comes as a tablet to take by mouth. It is usually taken three to four times a day. Take mitotane at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take mitotane exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

You will probably be hospitalized when you begin your treatment with mitotane. Your doctor will start you on a low dose of mitotane and gradually increase your dose.

Continue to take mitotane even if you feel well. Do not stop taking mitotane without talking to your doctor.

Other uses for this medicine

Mitotane is also sometimes used to treat Cushing's Syndrome (condition where the body produces too much of the hormone cortisol). Talk to your doctor about the risks of using this drug for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking mitotane,

- tell your doctor and pharmacist if you are allergic to mitotane, or any other medications.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: anticoagulants ('blood thinners') such as warfarin (Coumadin); antidepressants ('mood elevators'); medications for anxiety, mental illness, or seizures; sedatives, sleeping pills, or tranquilizers; and spironolactone (Aldactone). Your doctor may need to change the dose of your medications or monitor you carefully for side effects. Many other medications may also interact with mitotane, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor if you have or have ever had liver disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking mitotane, call your doctor.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking mitotane.
- you should know that mitotane may make you dizzy or drowsy. Do not drive a car or operate machinery until you know how this medication affects you.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Mitotane may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- loss of appetite
- nausea
- vomiting
- diarrhea
- depression
- lack of energy
- unusual drowsiness
- feeling that the room is spinning
- changes in vision

- rash or changes in skin color

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately:

- abdominal or side pain
- confusion
- fast heartbeat
- high fever or shaking chills
- excessive sweating

Mitotane may cause brain or nervous system damage when taken at high doses for longer than 2 years. Talk to your doctor about the risks of taking this medication.

Mitotane may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your body's response to mitotane.

Before having any laboratory test, tell your doctor and the laboratory personnel that you are taking mitotane.

Wear or carry medical identification stating that you take mitotane to be sure you get proper treatment in an emergency.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Lysodren[®]

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