

Mitotane

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for cancer of the adrenal glands (adrenocortical carcinoma).
- It may also be used for other reasons.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Mitotane (MY-toh-tane): Lysodren (LY-so-dren)	Slows the production of hormones that feed adrenal cancer to slow cancer growth.	Tablets taken by mouth.

Treatment Administration and Schedule

Your mitotane dosing instructions:

- Mitotane comes in 1 tablet strength: 500 mg.
- Your dose might differ, but mitotane is typically taken as 3 to 4 doses each day. Most people take between 2,000 mg and 6,000 mg each day.
- Do not change your dose unless your healthcare provider tells you to.
- You will need to get blood tests often. These tests help your care team make sure your dose is right for you.
- Take mitotane with food, preferably a high-fat meal or snack. Talk to your care team about examples of foods you should eat.
- Swallow mitotane tablets whole. Do not crush, chew, or split the tablets.
- Do not take any mitotane tablets that are broken or crushed.
- If you miss a dose of mitotane, skip the missed dose and take the next dose at your regularly scheduled time. Do not take 2 doses at the same time to make up for a missed dose.
- If you vomit after taking mitotane, take the next dose at your regularly scheduled time.
- If you take too much mitotane, call your care team right away or go to the nearest emergency room.

Storage and Handling of Mitotane

- Store mitotane at 77°F (25°C). You can store it for short periods of time between 59°F and 86°F (15°C and 30°C).
- Keep mitotane and all medicines out of the reach of children and pets.
- Whenever possible, give mitotane to yourself and follow the steps below. If someone else gives it to you, they must also follow these steps:
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. Note: Gloves are not needed if you give the drug to yourself.
 3. Transfer the mitotane from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves, if used, and throw them and medicine cup in household trash.
 6. Wash hands with soap and water.
- If you plan to use a daily pill box or pill reminder, contact your care team before using it.
 - When the box or reminder is empty, wash it with soap and water before refilling.
 - The person refilling the box or reminder should:
 - Wear gloves. Note: Gloves are not needed if you are refilling it yourself.
 - Wash their hands with soap and water after completing the task, regardless of whether gloves were worn.
- Ask your care team how to safely throw away any unused mitotane. Do not throw it in the trash or flush it down the sink or toilet.

Appointments: Appointments may include regular check-ups with your care team, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Taken at Home
To help prevent or treat nausea and vomiting	<hr/> <hr/> <hr/>
Other	<hr/> <hr/> <hr/>

Common Side Effects

Side Effect	Important Information
Diarrhea	<p>Description: Diarrhea is loose, watery stools or more frequent bowel movements than usual. It can cause dehydration and weakness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep track of how often you go to the bathroom each day. • Drink 8 to 10 glasses of water or other fluids daily, unless your care team tells you otherwise. • Eat small meals of mild, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). • If you have diarrhea, avoid high-fiber foods (such as raw vegetables, fruits, and whole grains), gas-producing foods (such as broccoli and beans), dairy (such as milk and yogurt), and spicy, fried, or greasy foods. • Your care team may recommend an antidiarrheal medicine such as loperamide (Imodium). <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • 4 or more bowel movements than normal in 24 hours • Dizziness or lightheadedness while having diarrhea • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Bloody diarrhea
Nausea and Vomiting	<p>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. You may or may not vomit.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Eat smaller, more frequent meals. • Avoid fatty, fried, spicy, or highly sweet foods. • Eat bland foods at room temperature and drink clear liquids. • If you vomit, start with small sips of water, broth, or other clear liquids. If these stay down, try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal) and gradually return to solid foods. • Your care team may prescribe medicine for these symptoms. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Vomiting for more than 24 hours • Nonstop vomiting • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Blood or coffee-ground-like appearance in your vomit • Severe stomach pain that does not go away after vomiting

Low Appetite

Description: Loss of appetite can lead to weight loss and low energy. Small changes in when and what you eat can help maintain strength and nutrition.

Recommendations:

- Be as active as you can. Do light physical activity before a meal (check with your care team before starting an exercise program).
- Note times of day when your appetite is best and eat your largest meal then.
- Eat 5–6 small meals or snacks each day.
- Choose high-protein foods (beans, chicken, fish, meat, yogurt, tofu, eggs). Eat protein first during meals.
- Choose higher-calorie foods (avoid “low-fat,” “fat-free,” or “diet” options when trying to gain/maintain weight).
- If you feel full quickly, avoid drinking 30 minutes before a meal and drink liquids between meals; choose calorie-containing drinks rather than diet drinks.
- Have a bedtime snack that’s easy to digest (for example, peanut butter and crackers). If you have reflux, wait at least 1 hour before lying down.
- Try nutritious beverages (high-protein shakes or smoothies) if solid food is unappealing.
- Ask your care team about liquid nutrition supplements and ways to add protein or calories (protein powder, yogurt, ice cream).

Talk to your care team if you have:

- Unintentional weight loss
- Little or no appetite for several days
- Excessive tiredness or low energy

<p>Rash or Itchy Skin</p>	<p>Description: Rash or itchy skin can cause redness, swelling, and a variety of bumps or patches (small red spots, welts, blisters, or scaly dry areas).</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep your skin moisturized with creams or lotions to reduce rash and itchiness. • Wear loose-fitting clothing. • Avoid perfumes and colognes, as they may worsen rash symptoms. • Limit time spent in the heat to prevent worsening symptoms. • Avoid sun exposure, especially between 10 AM and 4 PM, to lower the risk of sunburn. • Wear long-sleeved clothing with ultraviolet (UV) protection and broad-brimmed hats. • Apply broad-spectrum sunscreen (UVA/UVB) with sun protective factor (SPF) 30 or higher as directed. • Use lip balm with SPF 30 or higher. • Avoid tanning beds. • Your care team may recommend medicines for symptoms. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Rash or itching that continues to worsen
<p>High Cholesterol and Triglycerides Levels in Your Blood (Hyperlipidemia)</p>	<p>Description: Treatment can raise cholesterol and triglyceride levels in your blood. While cholesterol is needed by the body, high levels can increase the risk of heart disease. Triglycerides are blood fats, and very high levels may raise the long-term risk of inflammation of your pancreas (pancreatitis) or heart problems.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Adopt a diet low in saturated and trans fats, increase fiber intake, and engage in regular physical activity. • Maintain a healthy weight. • Get regular cholesterol tests and inform the care team of any significant changes. • Do not smoke and limit alcohol consumption. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Symptoms of heart attack or stroke, such as sudden numbness, weakness, or chest pain

<p>Low Thyroid Function (Hypothyroidism)</p>	<p>Description: Hypothyroidism means your thyroid gland is not making enough thyroid hormone. This can cause tiredness, feeling cold, weight gain, slow thinking, dry skin, hair loss, constipation, and changes in menstrual cycles.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> Your care team may perform blood tests to check your thyroid function before and during treatment. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> Increasing tiredness, weight gain, constipation, or feeling much colder than usual Slow thinking, slurred speech, or worsening depression Very heavy or changed menstrual bleeding Rapid heart rate, chest pain, or shortness of breath
<p>Low Testosterone</p>	<p>Description: Low testosterone means your body has less of the male sex hormone testosterone than normal. It can cause low energy, low sex drive, erectile problems, mood changes, reduced muscle mass, increased body fat, and fertility changes.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> Your care team may perform blood tests to check your testosterone levels before and during treatment. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> New or worsening erectile problems or loss of sexual function Sudden mood changes, severe depression, or thoughts of harming yourself Unexplained swelling, shortness of breath, or chest pain Breast swelling or lumps, or severe acne
<p>Depression</p>	<p>Description: Depression is more than feeling sad. It can cause long-lasting low mood, loss of interest in activities, changes in sleep or appetite, low energy, trouble concentrating, and feelings of worthlessness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> Tell your care team about mood changes or past depression before and during treatment. Keep a regular routine: sleep, meals, and gentle activity each day. Stay connected with friends, family, or support groups. Don't isolate. Try coping strategies such as short walks, relaxation exercises, journaling, or counseling. Avoid alcohol and drugs that can make your mood worse. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> New or worsening depression or anxiety Thoughts about harming yourself or wanting to die Extreme mood changes, confusion, or not recognizing people or places Inability to carry out daily activities (eating, bathing, going to work) Severe sleep problems, panic attacks, or signs of psychosis (seeing or hearing things that are not there)

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
<p>Adrenal Gland Problems: Adrenal Insufficiency and Adrenal Crisis (Boxed Warning)</p>	<p>Adrenal Insufficiency. Mitotane can cause your adrenal glands to stop making enough corticosteroid hormones (adrenal insufficiency) or make this problem worse in people with cancer of the adrenal glands (adrenocortical carcinoma). Your care team may temporarily stop, reduce your dose, or permanently stop treatment if you develop adrenal insufficiency during treatment.</p> <p>Adrenal Crisis. Mitotane can cause your adrenal glands to suddenly stop making enough corticosteroid hormones (adrenal crisis). You are at increased risk for developing an adrenal crisis if you experience shock, severe injury, or infection during treatment. Adrenal crisis may lead to death.</p> <p>Tell your care team right away if you get an injury, infection, or other illness during treatment with mitotane. Your care team may temporarily stop mitotane if shock, severe injury, or infections happen during treatment.</p> <p>Tell your care team if you have any planned surgery.</p> <p>Your care team will check your levels of corticosteroid hormones during treatment and may give you corticosteroid medicine if you develop adrenal gland problems.</p> <ul style="list-style-type: none"> • Severe weakness • Confusion • Pain in the lower back and legs • Stomach (abdominal) pain • Nausea, vomiting, or diarrhea • Feeling lightheaded or dizzy • Passing out • Feeling very tired • Decreased appetite • Weight loss • Areas of darkened skin • Craving salt • Low blood sugar • Feeling irritable or depressed • Hair loss
<p>Low White Blood Cell (WBC) Count (Neutropenia)</p>	<ul style="list-style-type: none"> • Fever of 100.4 °F (38°C) or higher • Chills • Burning and painful urination • Urinating often • Weakness and tiredness • Coughing up yellow or pink mucus (phlegm)
<p>Low Red Blood Cell (RBC) Count and Hemoglobin (Anemia)</p>	<ul style="list-style-type: none"> • Fatigue • Weakness • Pale or dull skin • Shortness of breath • Dizziness or lightheadedness • Cold hands and feet • Irregular heartbeat • Headaches • Chest pain

<p>Low Platelet Count (Thrombocytopenia)</p>	<ul style="list-style-type: none"> • Bruising easily • Frequent nose bleeds • Blood in your urine or stool • Blood in your spit after a cough
<p>Prolonged Bleeding Time</p>	<p>Mitotane can cause bleeding that lasts longer than usual. If you need to have surgery or dental procedures during treatment, your care team may do blood tests to check for prolonged bleeding risks. Tell your care team right away if you develop signs or symptoms of prolonged bleeding during treatment.</p> <ul style="list-style-type: none"> • Unusual bleeding or bleeding that will not stop • Bruising • Lightheadedness • Vomiting blood or your vomit looks like coffee grinds • Blood in your stool or black stool that looks like tar • Pink or brown urine • Coughing up blood or blood clots • Menstrual bleeding that is heavier than normal • Nose bleeds that happen often
<p>Neurologic Problems (Central Nervous System Toxicity)</p>	<p>Mitotane can cause decreased awareness and alertness.</p> <ul style="list-style-type: none"> • Slow thinking • Slow movement or decreased coordination • Confusion • Difficulty concentrating • Memory loss • Trouble talking • Sleepiness • Dizziness • Feelings of “pins and needles” in your hands and feet • Feeling very tired
<p>Liver Problems</p>	<ul style="list-style-type: none"> • Yellowing of your skin or the whites of your eyes • Severe nausea or vomiting, pain on the right side of your stomach area (abdomen) • Dark urine (tea colored) • Bleeding or bruising more easily than normal
<p>Ovarian Cysts</p>	<p>Mitotane can cause noncancerous large cysts (macrocyts) on the ovaries of people who have not gone through menopause or are just starting menopause (premenopausal). The cysts may cause pain or discomfort in your pelvic area and abnormal periods (menstruation), or they may not cause any symptoms at all. If you are premenopausal, your care team may do an ultrasound of your ovaries before starting mitotane and as needed during treatment.</p> <ul style="list-style-type: none"> • Vaginal pain • Pelvic pain

**Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.
If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.**

Intimacy, Fertility, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body**. However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment can affect your **ability to have children**. It may damage your reproductive organs or stop them from working. If you are worried about fertility, talk to your care team before starting treatment.
- Treatment may **harm an unborn baby**.
 - If you are able to become pregnant, take a pregnancy test before starting treatment.
 - Use effective birth control (contraception) that does not contain hormones (nonhormonal), such as condoms or diaphragms, and spermicide during treatment with mitotane and for as long as your care team tells you to after you stop treatment.
 - Talk to your care team about nonhormonal birth control methods that may be right for you.
 - Birth control methods that contain hormones, such as birth control pills, injections, or patches, may not work as well during and after treatment with mitotane.
 - If you think you might be pregnant or if you become pregnant, tell your care team right away.
 - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment and for as long as your care team tells you to after you stop treatment.
- **Do NOT breastfeed** during treatment and after you stop taking mitotane until your care team tells you it is okay. Talk to your care team about the best way to feed your baby during and after treatment with mitotane.

Handling Body Fluids and Waste

Some drugs you receive may stay in your urine, stool, sweat, or vomit for many days after treatment. Because many cancer drugs are toxic, your bodily waste may also be dangerous to touch. To help protect yourself, your loved ones, and the environment, **follow these instructions** for at least **8 months** after each dose of **mitotane**:

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- You can use your usual toilet. Always close the lid and flush to discard all waste. If you have a low-flow toilet, flush twice.
- If the toilet or seat is soiled with urine, stool, or vomit, clean the surface after each use before others use it.
- Wash your hands with soap and water for at least 20 seconds after using the toilet.
- If you need a bedpan, inform your caregiver so they can wear gloves and assist with cleanup. Wash the bedpan with soap and water daily.
- If you cannot control your bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb waste.
- Wash any skin exposed to body waste with soap and water.
- Wash soiled linens or clothing separately from other laundry. If you don't have a washer, place them in a plastic bag until they can be washed.
- Wash your hands with soap and water after touching soiled linens or clothing.

Additional Information

- **Tell your care team about all the medicines you take.** This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
Especially tell your healthcare provider if you take:
 - Spironolactone
 - Hormonal birth control
 - Warfarin
 - Midazolam or other CYP3A substrates
- **Do not** drive or operate heavy machinery until you know how mitotane affects you. Mitotane may cause sleepiness, decreased energy, and dizziness, which may affect your ability to drive and operate machinery.
- **This Patient Education Sheet may not describe all possible side effects.**
Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

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Scan the QR code below to access this education sheet.



Important notice: The Association of Cancer Care Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), Network for Collaborative Oncology Development & Advancement, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources.

This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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