

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**Pr LYSODREN®**

**Mitotane Tablets**

Read this carefully before you start taking **LYSODREN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LYSODREN**.

#### **Serious Warnings and Precautions**

At high doses, LYSODREN can cause severe brain damage and problems with how the brain works. This is called neurologic toxicity. If you are taking high doses of LYSODREN, your healthcare professional will monitor your behaviour and how your brain is working.

#### **What is LYSODREN used for?**

LYSODREN is used to treat a type of cancer that affects the adrenal gland. This cancer is called adrenal cortical carcinoma of functional or non-functional type. Patients who take Lysodren have a cancer that cannot be removed by surgery.

#### **How does LYSODREN work?**

Mitotane is the active ingredient in LYSODREN. The way it works is not exactly known. However, it seems to affect how steroids are broken down. As well, it seems to stop the activity of the adrenal cortex. This is where the cancer is located.

#### **What are the ingredients in LYSODREN?**

Medicinal ingredients: mitotane

Non-medicinal ingredients: colloidal silicon dioxide, corn starch, microcrystalline cellulose, polyethylene glycol

#### **LYSODREN comes in the following dosage forms:**

Tablet: 500 mg

#### **Do not use LYSODREN if:**

- You are allergic to mitotane or to any other ingredients in this medicine

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LYSODREN. Talk about any health conditions or problems you may have, including if you:**

- have recently experienced a shock or severe trauma

- have or have had liver problems
- take medication that acts on your central nervous system
- are overweight or obese
- have recently lost weight
- have recently had or plan to have a surgery
- have metastases. This means that your cancer has spread outside of the adrenal gland.

**Other warnings you should know about:**

**Adrenal insufficiency** can happen with LYSODREN treatment. This is when the adrenal glands don't make enough of the hormone cortisol. If you experience adrenal insufficiency, you may need to take other medicines.

Cysts on the ovaries (called **ovarian macrocysts**) are possible in women treated with LYSODREN. If you are a woman and you have unusual vaginal bleeding or pain in the pelvis, contact your healthcare professional. If you are post-menopausal, you may need ultrasound scans of your ovaries.

**Female patients – Pregnancy and breastfeeding:**

- If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your healthcare professional.
- Avoid becoming pregnant while you are taking LYSODREN. It may harm your unborn baby.
- If you are able to get pregnant, use effective birth control during your treatment. You must also use this birth control after stopping LYSODREN. Your healthcare professional will do blood tests to determine when you can stop using this birth control. It will depend on the results of these tests.
- Do not breastfeed while you are taking LYSODREN. Mitotane may pass into your breastmilk. Your healthcare professional will tell you when you can start breastfeeding. It will depend on blood test results.

**Driving and operating machines:** LYSODREN can affect your brain and nervous system. This may affect your ability to drive and use machines. Ask your healthcare professional for advice.

**Blood tests:**

- Your healthcare professional will do blood tests during your treatment. These tests will be done regularly (e.g. monthly).
  - If you are overweight or have recently lost weight, these tests may be done every 2 weeks.
  - If you are taking blood thinners like warfarin, you will have regular blood tests to see if there are changes in how clots form in your blood.
- Tell your healthcare professional that you are taking LYSODREN each time you have blood work. It can affect some blood tests.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with LYSODREN:**

- steroid replacement therapy (such as cortisol, hydrocortisone, prednisolone or dexamethasone)
- medicines used as blood thinners like warfarin
- the anti-cancer drug called etoposide
- medicines that act on the central nervous system

**How to take LYSODREN:**

- This medicine should not be handled by persons other than the patient and his/her caregivers, and especially not by pregnant women. Always wear gloves when handling the LYSODREN bottle and tablets. If you touch broken tablets, wash thoroughly with soap and water right away.
- Do not crush, break, split or cut the tablets.
- Swallow the tablets whole with a glass of water.
- Take your LYSODREN with a meal that contains foods high in fat like milk, chocolate or oil.

**Usual dose:**

Your healthcare professional will tell you how much and how often to take LYSODREN. Do not take more than you are told.

**Overdose:**

Too much LYSODREN can cause severe brain damage that can cause dizziness or problems with memory, speech, attention or balance.

If you think you, or a person you are caring for, have taken too much LYSODREN, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss a dose, skip it. Take your next dose as per your usual schedule. Do not take two doses at once to make for the missed dose.

**What are possible side effects from using LYSODREN?**

These are not all the possible side effects you may have when taking LYSODREN. If you experience any side effects not listed here, tell your healthcare professional.

- Loss of appetite
- Nausea, vomiting
- Diarrhea
- Depression
- Lethargy (lack of energy), weakness, drowsiness
- Dizziness, vertigo

- Skin rashes
- Blurred or double vision
- Blood in urine
- High blood pressure
- Quick drop of blood pressure when you stand up, that can cause dizziness, lightheadedness or fainting
- Flushing
- Fever
- Body aches
- Growth of breast in men
- Sex hormones disturbances in males and females
- Delayed growth

LYSODREN can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment and will interpret the results.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>RARE/UNKNOWN</b>			
<b>Adrenal insufficiency</b> (adrenal glands don't make enough cortisol): fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain, nausea, vomiting			x
<b>Albuminuria</b> (proteins in urine): swelling of the ankles, hands, abdomen or the face		x	
<b>Hemorrhagic cystitis</b> (bladder inflammation): pain, discomfort, or burning when urinating, blood in urine		x	
<b>Hepatitis</b> (inflammation of the liver): fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, light-colored stools, joint pain, jaundice		x	
<b>Hypogonadism in males</b> (the body doesn't make enough testosterone): enlarged breast, libido decreased, erectile dysfunction, fertility disorders		x	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Hypothyroidism</b> (underactive thyroid gland): fatigue, sensitivity to cold, constipation, dry skin, weight gain, swelling of the face, voice changed, muscle weakness		x	
<b>Lens opacity</b> (clouding of the lens of the eye): loss of vision, blurry or double vision, halos around light, trouble with bright lights, faded colors		x	
<b>Leukopenia</b> (low white blood cells): mouth or skin sores, sore throat, cough, trouble breathing, feeling light-headed, fever, chills, sweating, body aches		x	
<b>Maculopathy</b> (a disease of the centre part of the retina called the macula): loss of vision, image distortion, central spot in vision		x	
<b>Neurologic toxicity and brain damage:</b> severe headache, difficulty speaking or slurred speech, loss of muscle coordination, loss of balance, mental impairment, confusion			x
<b>Ovarian macrocysts</b> (fluid-filled sacs on the ovaries): bloating, lower abdominal / pelvic pain, lower back pain, vaginal bleeding		x	
<b>Toxic retinopathy:</b> loss of vision, diminished color vision, trouble reading		x	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Store in the original packaging at room temperature (15-30°C).

Keep out of sight and reach of children.

Do not use after the expiry date which is stated on the carton and the bottle after EXP.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **If you want more information about LYSODREN:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>) or the manufacturer's website ([www.hra-pharma-rare-diseases.com](http://www.hra-pharma-rare-diseases.com)).

This leaflet was prepared by HRA Pharma Rare Diseases.

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