

PATIENT INFORMATION
ORSERDU™ (or-SER-doo)
(elacestrant)
tablets

What is ORSERDU?

ORSERDU is a prescription medicine to treat women who have gone through menopause and adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, *ESR1*-mutated advanced breast cancer or breast cancer that has spread to other parts of the body (metastatic), **and** whose disease has progressed after endocrine therapy.

Your healthcare provider will perform a test to make sure that ORSERDU is right for you.

It is not known if ORSERDU is safe and effective in children.

Before taking ORSERDU, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- are pregnant or plan to become pregnant. ORSERDU can harm your unborn baby.
Females who are able to become pregnant:
 - Your healthcare provider may do a pregnancy test before you start treatment with ORSERDU.
 - You should use effective (contraception) birth control during treatment with ORSERDU and for 1 week after the last dose.
 - Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with ORSERDU.
- **Males with female partners who are able to become pregnant:**
 - You should use effective (contraception) birth control during treatment with ORSERDU and for 1 week after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if ORSERDU passes into your breast milk. Do not breastfeed during treatment with ORSERDU and for 1 week after the last dose.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ORSERDU and other medicines may affect each other causing side effects. Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take ORSERDU?

- Take ORSERDU exactly as your healthcare provider tells you.
- Do not change your dose or stop taking ORSERDU unless your healthcare provider tells you.
- Take ORSERDU 1 time each day, at about the same time each day.
- Take ORSERDU with food. Taking ORSERDU with food may help reduce nausea and vomiting.
- Swallow ORSERDU tablets whole. Do not chew, crush or split the tablets before swallowing.
- Do not take any ORSERDU tablets that are broken, cracked, or that look damaged.
- If you miss a dose of ORSERDU or vomit after taking a dose of ORSERDU, do not take another dose of ORSERDU on that day. Skip the dose and take your next dose the following day at your regularly scheduled time.

What are the possible side effects of ORSERDU?

ORSERDU may cause serious side effects, including:

- **Increased fat (lipid) levels in your blood (hypercholesterolemia and hypertriglyceridemia).** Your healthcare provider will do blood tests to check your lipid levels before and during your treatment with ORSERDU.

The most common side effects of ORSERDU include:

- muscle and joint (musculoskeletal) pain
- nausea
- increased cholesterol and triglyceride levels in your blood
- increased liver function tests
- tiredness
- decreased red blood cell counts
- vomiting
- decreased salt (sodium) levels in your blood
- increased kidney function test
- decreased appetite
- diarrhea
- headache
- constipation
- stomach-area (abdominal) pain
- hot flush
- indigestion or heartburn

Your healthcare provider may decrease your dose, temporarily stop, or completely stop treatment with ORSERDU, if you develop certain side effects.

ORSERDU may affect fertility in males and in females who are able to become pregnant. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of ORSERDU.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ORSERDU?

- Store ORSERDU at room temperature 68°F to 77°F (20°C to 25°C).

Keep ORSERDU and all medicines out of the reach of children.

General information about the safe and effective use of ORSERDU.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ORSERDU for a condition for which it was not prescribed. Do not give ORSERDU to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for more information about ORSERDU that is written for health professionals.

What are the ingredients in ORSERDU?

Active ingredient: elacestrant

Inactive ingredients: colloidal silicon dioxide, crospovidone, magnesium stearate (non-bovine), microcrystalline cellulose, silicified microcrystalline cellulose and Opadry II Blue (polyvinyl alcohol, titanium dioxide, polyethylene glycol, FD&C Blue #1 and talc).

ORSERDU is a trademark of the Menarini Group.

©Stemline Therapeutics, Inc., a Menarini Group Company

Manufactured for: Stemline Therapeutics, Inc., New York, NY 10022

For more information, go to www.ORSERDU.com or call 1-877-332-7961

This Patient Information has been approved by the U.S. Food and Drug Administration.

Issued: 01/2023