

IMPORTANT FACTS

This is only a brief summary of important information about ORSERDU. Talk to your healthcare provider or pharmacist to learn more.

ABOUT ORSERDU

ORSERDU (or-SER-doo) 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 TO TAKE ORSERDU

- 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.

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:

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

GET MORE INFORMATION

This is only a brief summary of important information about ORSERDU. Talk to your healthcare provider or pharmacist to learn more.

Go to [ORSERDU.com](https://www.orserdud.com) for the full Prescribing Information, which is written for healthcare professionals.

If you need financial assistance, visit [StemlineARC.com](https://www.stemlinearc.com) for program information.