

Frequently Asked Questions About ORSERDU™ (elacestrant)

1 What is ORSERDU?

ORSERDU is a type of hormone therapy called a *selective estrogen receptor antagonist/degrader*. Hormone therapies work by helping to block estrogen from getting to the cells that drive breast cancer growth in patients with estrogen receptor (ER)-positive metastatic breast cancer (mBC). Without estrogen, the cancer cells may not grow, or they grow more slowly. Hormone therapies have been used to treat people with mBC for more than 2 decades. ORSERDU is different and represents the first new endocrine therapy approved in approximately 20 years, and is the first oral treatment for patients with ER+/human epidermal growth factor receptor 2 (HER2)-negative mBC with estrogen receptor 1 mutation (*ESR1* mutation).

2 Who is a candidate for 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.

3 How is ORSERDU administered?

ORSERDU is a once-daily oral medication that should be taken at the same time each day with food. Always take ORSERDU exactly as your healthcare team prescribes.

- Pills should be swallowed whole. Do not chew, crush, or split pills
- If a dose is missed for more than 6 hours, take your normal dose on the following day at the scheduled time
- Don't stop taking ORSERDU unless a member of your healthcare team tells you to stop

4 How effective is ORSERDU?

In clinical trials, ORSERDU worked better than certain commonly prescribed hormone therapies.

Treatment with ORSERDU was evaluated in a 2-year clinical study that included a diverse group of people, with 228 people who had ER+/HER2- mBC with an *ESR1* mutation and had progressed on or after endocrine therapy. The median time people with an *ESR1* mutation were progression-free from the start of treatment was 3.8 months for ORSERDU vs 1.9 months for other commonly prescribed hormone therapies which included fulvestrant or an aromatase inhibitor. Participants who had an *ESR1* mutation and who had been on a CDK 4/6 inhibitor for at least 12 months experienced a median of 8.6 months without the cancer progressing, compared to 1.9 months for those in the control group.

5 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

Before you start ORSERDU, tell your healthcare provider if you are pregnant or may become pregnant as 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

The most common (>10%) side effects included:

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

Other common side effects (<10%) included:

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| • rash | • cough | • swelling or sores inside the mouth |
| • insomnia | • dizziness | • acid reflux |
| • shortness of breath | | |

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. Remember to let your doctor or healthcare team know if you experience any side effects during treatment.

Please see the Important Safety Information for ORSERDU on the following page and please see the accompanying Full Prescribing Information, including Patient Information.

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What is *ESR1* mutation?

ESR1 mutation is a type of resistance mutation that sometimes develops after cancer is treated with certain drugs or therapies. Up to 40% of HR+/HER2- mBC cases develop an *ESR1* mutation after progression on initial endocrine therapy. Your healthcare provider can test your cancer for an abnormal “*ESR1*” gene to determine if you may be candidate for ORSERDU. Testing for *ESR1* mutations should take place at progression in the metastatic treatment.

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How do I get this medication?

ORSERDU is specifically approved for people with *ESR1*-mutated mBC, so your healthcare provider will need to test your cancer for an abnormal “*ESR1*” gene to see if ORSERDU may be right for you. If your healthcare provider determines that you are a candidate and prescribes ORSERDU, your healthcare team will work with you to help you obtain your medication. For more information about the Stemline ARC Patient Support Program visit www.stemlinearc.com.

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Where can you find answers to additional questions?

Please visit <http://www.ORSERDU.com>, call 1-877-332-7961, or email StemlineUS@druginfo.com for additional information.

IMPORTANT SAFETY INFORMATION

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.

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.

The most common side effects included:

- muscle and joint (musculoskeletal) pain
 - decreased red blood cell counts
 - diarrhea
 - nausea
 - vomiting
 - headache
 - increased cholesterol and triglyceride levels in your blood
 - decreased salt (sodium) levels in your blood
 - constipation
 - increased liver function tests
 - increased kidney function test
 - stomach-area (abdominal) pain
 - tiredness
 - decreased appetite
 - 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 the possible side effects of ORSERDU. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see the accompanying Full Prescribing Information, including Patient Information.

