

ONCE-DAILY TABLET

The first and only treatment for people with *ESR1*-mutated ER+/HER2- advanced or metastatic breast cancer following disease progression on endocrine therapy

Your treatment guide

 **ORSERDU**[®]
elacestrant



Not an actual patient.

ER+, estrogen receptor-positive; *ESR1*, estrogen receptor 1; HER2-, human epidermal growth factor receptor 2-negative.

INDICATION

ORSERDU (elacestrant) 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.

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

Learn more at [ORSERDU.com](https://www.orserdu.com)

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Patient Information, for ORSERDU.



Stemline[®]
A Menarini Group Company

Understanding your treatment with ORSERDU

While you are being treated for advanced or metastatic breast cancer, it's important to know what to expect. You may also want to learn more about your type of cancer and why your doctor has prescribed ORSERDU.

Inside this guide, you'll find information about ORSERDU, including:

- Understanding *ESR1* mutations
- About ORSERDU
- ORSERDU results
- Taking ORSERDU
- What to expect with ORSERDU
- Talking with your healthcare team
- Support resources

IMPORTANT SAFETY INFORMATION (continued)

Before taking ORSERDU, tell your healthcare provider about all 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



Consider asking your healthcare team:

- Why was ORSERDU chosen for my next treatment?
- When can I start taking ORSERDU?



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Mutations may develop **after taking certain hormone therapies**



***ESR1* mutations may cause treatment resistance**

Sometimes cancer becomes resistant to treatment (treatment stops working). This can happen because cancer cells have changed, or “mutated.” Mutations can cause resistance to certain hormone therapies.

An *ESR1* mutation is a common resistance mutation. It is most likely found after cancer has progressed (spread, grown, or gotten worse), and current treatment is no longer working.



How hormone therapies work

Hormone therapies help to block estrogen from getting to ER+ breast cancer cells. Without estrogen, the cancer cells may not grow, or they may grow more slowly. Acquired *ESR1* mutations can cause some hormone therapies to stop working and cancer to progress.

Hormone therapies have been used to treat people with advanced or metastatic breast cancer for more than 2 decades.

Some of these hormone therapies include:

- **exemestane**
- **anastrozole**
- **letrozole**
- **fulvestrant**



Metastatic breast cancer cells travel in the bloodstream

When breast cancer is advanced or metastatic, breast cancer cells enter the bloodstream or lymphatic system. New tumors can form in other parts of the body, including bones, liver, lungs, and brain.



Consider asking your healthcare team:

- **What might have caused my cancer to develop an *ESR1* mutation?**
- **How do *ESR1* mutations cause cancer to progress?**



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Your doctor has prescribed **ORSERDU** for your metastatic breast cancer with an *ESR1* mutation

ORSERDU is different.

It is not an injection, infusion, or chemotherapy. ORSERDU is a type of oral hormone therapy called an estrogen receptor antagonist.

ESR1 mutations are common. You are not alone.

Nearly **1 out of 2** (~50%) people with ER+/HER2- metastatic breast cancer may develop an *ESR1* mutation after progression on hormone therapy.

It's important to talk about your type of cancer and treatment options with your healthcare team. This way, you can make decisions together.

ORSERDU is the **first and only treatment** for postmenopausal women and adult men with ***ESR1*-mutated ER+/HER2- advanced or metastatic breast cancer** following disease progression on endocrine therapy.

Nearly **1 out of 2**



Consider asking
your healthcare team:

- **What more should I know about this type of mutation?**
- **Is ORSERDU only for people with my kind of cancer?**



Not an
actual patient.

IMPORTANT SAFETY INFORMATION (continued)

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

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

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Patient Information, for ORSERDU.

How ORSERDU was studied

ORSERDU was studied over **2 years in 228 patients** to see if it would stop or slow progression in *ESR1*-mutated ER+/HER2- advanced or metastatic breast cancer. When cancer progresses, it spreads, grows, or gets worse.

In the clinical study, ORSERDU was compared with common hormone therapies such as exemestane, anastrozole, letrozole, and fulvestrant. No one was given a placebo (sometimes called a sugar pill).

All people in the clinical study had previously taken a type of treatment called a CDK4/6 inhibitor. These included treatments such as Ibrance[®] (palbociclib), Kisqali[®] (ribociclib), and Verzenio[®] (abemaciclib).

In the clinical study, ORSERDU was given alone. It was not given in combination with any other therapies. See results from the clinical study in the next section.

Ibrance is a registered trademark of Pfizer Inc. Kisqali is a registered trademark of Novartis AG. Verzenio is a registered trademark owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.



Consider asking your healthcare team:

- **What do I have in common with people from the clinical study?**
- **How will I take ORSERDU?**



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IMPORTANT SAFETY INFORMATION (continued)

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

- 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

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Patient Information, for ORSERDU.

ORSERDU can give you **more time without disease progression**

ORSERDU helped people live 2x longer without their disease spreading, growing, or getting worse.



Median progression-free survival (mPFS) is a type of time measurement in a clinical trial. It measures the point in time when half of the people in the trial were living without their disease spreading, growing, or getting worse. The mPFS for people with *ESR1*-mutated cancer from the start of treatment was 3.8 months for ORSERDU vs 1.9 months for other commonly prescribed hormone therapies. Individual results may vary.

45% **less risk of disease progression with ORSERDU**
In the clinical study, people who took ORSERDU had a 45% reduction in the risk of their cancer growing, spreading, or getting worse when compared to people who took other hormone therapies.

IMPORTANT SAFETY INFORMATION (continued)

Tell your healthcare provider about all 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.



Consider asking your healthcare team:

- What could these results mean for me?



Not an actual patient.

What to expect while taking ORSERDU

Warnings and precautions



ORSERDU may cause serious side effects including:

- ORSERDU may cause the serious side effect of increasing fat (lipid) levels in your blood, also known as 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 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:

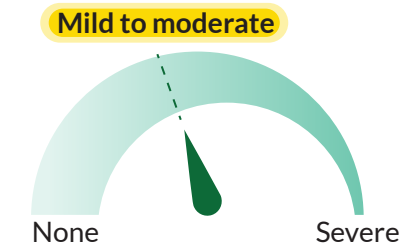
- Your healthcare provider may do a pregnancy test before you start treatment with ORSERDU
- You should use effective (contraception) birth control during treatment with ORSERDU and for 1 week after the last dose
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant 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

In the clinical study, most side effects were classified as mild to moderate

Most people did not need to take anti-nausea medication while taking ORSERDU.



Some of the most common side effects included (≥10%):

- Muscle and joint pain
- Headache
- Nausea
- Diarrhea
- Tiredness
- Hot flush
- Vomiting
- Constipation
- Decreased appetite

Additional side effects (≥10%) included increased cholesterol and triglyceride levels in your blood, increased liver function tests, decreased red blood cell counts, decreased salt (sodium) levels in your blood, increased kidney function test, stomach-area (abdominal) pain, and indigestion or heartburn.

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

3%

of the people in the clinical study needed to reduce treatment with ORSERDU due to side effects

6%

of the people in the clinical study stopped taking ORSERDU due to side effects

15%

of the people in the clinical study had to interrupt their treatment with ORSERDU due to side effects



Consider asking your healthcare team:

- What situation(s) might require me to stop or change my dose of ORSERDU?

Not an actual patient.

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Patient Information](#), for ORSERDU.

Take ORSERDU **once a day, every day, from anywhere**

Always take ORSERDU exactly as your healthcare team prescribes.



Take ORSERDU at about the same time each day.

Pill not actual size

- If a dose is missed, take your normal dose on the following day*
- Do not change your dose or stop taking ORSERDU unless your healthcare provider tells you

*If a dose is missed at the scheduled time, it can still be taken if less than 6 hours have passed. If more than 6 hours have passed after the scheduled dosing time, then the missed dose should be skipped, and regular dosing should resume the next day.



Take ORSERDU with food.

- This may help to reduce nausea and vomiting
- Pills should be swallowed whole. Do not chew, crush, or split pills



ORSERDU may be taken anywhere (at home or on the go).

Before you start taking ORSERDU, talk with your healthcare team about any questions or concerns you may have. It's also important to read the Patient Information and Important Safety Information.

It's important to take ORSERDU as directed. Don't stop taking it without your doctor's direction.

Let your doctor or healthcare team know if you experience any side effects. Tell your healthcare team about all 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.

ORSERDU is available as 345-mg and 86-mg tablets.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Patient Information, for ORSERDU.



Consider asking your healthcare team:

- How long can I expect to take ORSERDU?
- Are there any foods I should avoid eating while taking ORSERDU?

IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of ORSERDU include:

- | | | |
|---|--|---------------------------------|
| • Muscle and joint (musculoskeletal) pain | • Vomiting | • Constipation |
| • Nausea | • Decreased salt (sodium) levels in your blood | • Stomach-area (abdominal) pain |
| • Increased cholesterol and triglyceride levels in your blood | • Increased kidney function test | • Hot flush |
| • Increased liver function tests | • Decreased appetite | • Indigestion or heartburn |
| • Tiredness | • Diarrhea | |
| • Decreased red blood cell counts | • Headache | |

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 may report side effects to the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.



Not an actual patient.

Talk with your healthcare team about your experience



You play an important role in your care. Take part in your treatment decisions. Speak openly and honestly with your healthcare team so that they understand your goals and preferences. Knowing what to expect and speaking up will help you get the most out of your treatment experience.

Here are some questions to help get you started:

- ✓ Is there anything more I should know about this type of mutation?
- ✓ How long can I expect to take ORSERDU?
- ✓ What kind of results can I expect from ORSERDU?
- ✓ How will I know if ORSERDU is the right treatment for me?
- ✓ How often will I need to come into the clinic for any type of monitoring or testing?
- ✓ What else can I expect while taking ORSERDU?
- ✓ When should I contact my doctor or nurse?
- ✓ What should I know or do before my next office visit?

Additional tips:

- If possible, take a family member or friend to your appointments for support
- Come prepared to your appointments: take notes and ask questions
- Ask your healthcare team members to repeat or write down information
- Before your next appointment, write down any changes to your overall health, treatment side effects you are experiencing, and/or changes in your daily routine

Take ORSERDU every day as directed. If you experience any side effects, let your doctor or healthcare team know. They can help you manage certain side effects or provide other advice to help ensure that you receive appropriate treatment.

Before you start taking ORSERDU, talk with your healthcare team about any questions or concerns you may have.

Get support throughout treatment with Stemline ARC[®]

Stemline ARC provides access support, reimbursement assistance, and educational resources to help you focus on your health throughout treatment, including:



Understanding and navigating your insurance



Financial assistance programs and options for eligible patients



Educational resources for you and your healthcare team to help you access treatment with ORSERDU

It's the ORSERDU team's goal to create tools and resources that may help you have a positive experience while being treated for advanced or metastatic breast cancer with an *ESR1* mutation.

Stemline ARC Patient Advocates provide a **single point of contact**

Stemline ARC Patient Advocates are here to provide ongoing support, connect you to helpful resources, and answer questions during your treatment. It's important to remember that support from Stemline ARC Patient Advocates is not intended to replace discussions between you and your healthcare team.



Here are some questions Stemline ARC Patient Advocates can help answer:

- How can I get financial assistance during my treatment?
- How can I get insurance coverage for ORSERDU?
- How do I handle getting reimbursed through insurance?
- Where can I learn more about ER+/HER2-metastatic breast cancer?

Enroll in Stemline ARC today.
Visit stemlineARC.com



See what treatment with ORSERDU can offer you



Pill not actual size

With ORSERDU | 3.8 months

With certain other hormone therapies | 1.9 months

2x longer

Once-daily dosing at home or on the go

2x longer without your cancer spreading, growing, or getting worse

mPFS: 3.8 months for ORSERDU vs 1.9 months for other commonly prescribed hormone therapies

Learn more about your treatment at [ORSERDU.com](https://www.orserdud.com)

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