

For postmenopausal women and adult men with *ESR1*-mutated, ER+/HER2- advanced or metastatic breast cancer following disease progression on endocrine therapy

WHEN IT'S ***ESR1***,  
IT'S THE



Not an actual patient.

***FOR ME***

## Your guide for treatment with ORSERDU

### 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.

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

### 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

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elacestrant

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

# Understanding treatment with ORSERDU, **the 1 for me**

It's important to know what to expect from your treatment for advanced or metastatic breast cancer. You may also want to learn more about your type of cancer and why your doctor has prescribed ORSERDU. ORSERDU works specifically against *ESR1*-mutated metastatic breast cancer. It's also a convenient, once-daily pill you can take at home or on the go.



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

- About ORSERDU
- ORSERDU results
- ORSERDU safety
- Taking ORSERDU
- Helpful resources
- Savings and support

## **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

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**Consider asking your healthcare team:**

- Why was ORSERDU chosen for my next treatment?
- How should I track my treatment experience?

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# ORSERDU is the **1** for me because it **treats cancer that has an *ESR1* mutation**

## ORSERDU is different

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



It's also the **only** FDA-approved treatment for your specific type of cancer.

ORSERDU is 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**



***ESR1* mutations are common.  
You are not alone.**

By now, you know that you are part of the nearly **1 out of 2** (~50%) people whose metastatic breast cancer may develop an *ESR1* mutation after progression on hormone therapy.

## 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

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Consider asking your healthcare team:

- Where can I learn more about *ESR1* mutations?
- How is my treatment different from chemotherapy?

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# How the **1** for me **was studied**

**ORSERDU** was studied:

over **2 years**  
in **228 people**

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 had previously taken a type of treatment called a CDK4/6 inhibitor**. These included treatments such as Ibrance<sup>®</sup> (palbociclib), Kisqali<sup>®</sup> (ribociclib), and Verzenio<sup>®</sup> (abemaciclib)
- ORSERDU was given alone. It was not given in combination with any other therapies

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.

CDK, cyclin-dependent kinase.

## **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

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**Consider asking your healthcare team:**

- What do I have in common with people from the clinical study?
- What could these results mean for me?

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# The **1** for me can offer **more time** **without disease progression**

ORSERDU works specifically against *ESR1*-mutated metastatic breast cancer. It helped people live 2x longer without their disease spreading, growing, or getting worse.



The median progression-free survival (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.

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.

**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.

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Consider asking your healthcare team:

- How will I know if my treatment is working?

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# What to expect while taking ORSERDU

## Warnings and precautions



### ORSERDU may cause serious side effects

- 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 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

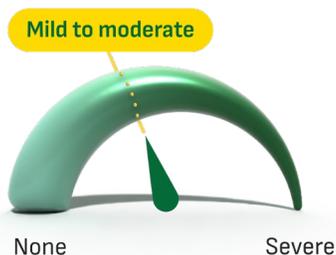
## Some of the most common side effects included ( $\geq 10\%$ ):

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

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Additional side effects ( $\geq 10\%$ ) 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.



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.

### Of the people in the clinical study:

**3%** needed to reduce treatment with ORSERDU due to side effects

**6%** stopped taking ORSERDU due to side effects

**15%** had to interrupt their treatment with ORSERDU due to side effects

Not actual patients.



Consider asking your healthcare team:

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

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

## Once a day, every day

Always take ORSERDU exactly as your healthcare team prescribes



Pill not  
actual size.

### Take ORSERDU at about the same time each day

- 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.

### IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of ORSERDU include:

- Muscle and joint (musculoskeletal) pain
- Nausea
- Increased cholesterol and triglyceride levels in your blood
- Increased kidney function test
- Decreased appetite
- Diarrhea

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**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: (continued)**

- Increased liver function tests
- Tiredness
- Decreased red blood cell counts
- Vomiting
- Decreased salt (sodium) levels in your blood
- 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.**

ORSERDU is available as 345 mg and 86 mg tablets.

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](http://www.fda.gov/medwatch).

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

## 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 they understand your goals and preferences. Knowing what to expect and speaking up will help you get the most out of your treatment experience with ORSERDU.

### Here are some questions to help get you started:

-  Is there anything more I should know about *ESR1* mutations?
-  How long can I expect to take ORSERDU?
-  What kind of results can I expect from ORSERDU?
-  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 you receive appropriate treatment.

Not an  
actual patient.



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

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## Get support throughout treatment with Stemline ARC<sup>®</sup>

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 goal of Stemline ARC to provide tools and resources to 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](https://stemlineARC.com)**

# SEE WHAT THE **1** FOR ME CAN OFFER



Not an actual patient.



**Once-daily**  
dosing at home  
or on the go  
Pill not actual size.



**More time** without your cancer  
spreading, growing, or getting worse  
mPFS: 3.8 months for ORSERDU vs 1.9 months  
for other commonly prescribed hormone therapies



**The first FDA-approved treatment**  
specifically for certain people  
with *ESR1*-mutated metastatic  
breast cancer

## 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.

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- Vomiting
- Decreased salt (sodium) levels in your blood
- Increased kidney function test
- Decreased appetite
- Diarrhea
- Headache
- Constipation
- Stomach-area (abdominal) pain
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