



## Access, Distribution, and Reimbursement Guide

### INDICATION

ORSERDU (elacestrant) 345 mg tablets are indicated for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

### IMPORTANT SAFETY INFORMATION

#### Warnings and Precautions

- **Dyslipidemia:** Hypercholesterolemia and hypertriglyceridemia occurred in patients taking ORSERDU at an incidence of 30% and 27%, respectively. The incidence of Grade 3 and 4 hypercholesterolemia and hypertriglyceridemia were 0.9% and 2.2%, respectively. Monitor lipid profile prior to starting and periodically while taking ORSERDU.

Please see additional Important Safety Information on [pages 17 and 18](#) and full [Prescribing Information](#) for ORSERDU to learn more.

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Please see Important Safety Information on pages 17 and 18 and full [Prescribing Information](#) for ORSERDU to learn more.



# ORSERDU Product Information

## Indication<sup>1</sup>

ORSERDU is indicated for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

## Dosing and Administration<sup>1</sup>

Select patients for treatment of ER-positive, HER2-negative advanced or metastatic breast cancer with ORSERDU based on the presence of an *ESR1* mutation(s) in plasma specimen using an FDA-approved test.

### Convenient daily oral dosing with ORSERDU



- One 345 mg tablet, once daily
- Treat patients until disease progression or unacceptable toxicity occurs



- Take with food
- Tablets should be swallowed whole. Do not chew, crush, or split prior to swallowing



- Should be taken around the same time, each day
- If a dose is missed for more than 6 hours, patient should continue regular dosing the next day\*

\*If a dose is missed for more than 6 hours or vomiting occurs, skip the dose and take the next dose the following day at its regularly scheduled time.

## Dosage Modifications<sup>1</sup>

- Some situations may require dose interruption, discontinuation, or adjustment. For information on dose modifications, please see the full [Prescribing Information](#)

## Storage<sup>1</sup>

- Store at 68°F to 77°F (20°C to 25°C)
- Excursions permitted from 59°F to 86°F (15°C to 30°C)

FDA=US Food and Drug Administration.

## IMPORTANT SAFETY INFORMATION (cont'd)

### Warnings and Precautions (cont'd)

- **Embryo-Fetal Toxicity:** Based on findings in animals and its mechanism of action, ORSERDU can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ORSERDU and for 1 week after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ORSERDU and for 1 week after the last dose.

Please see additional Important Safety Information on pages 17 and 18 and full [Prescribing Information](#) for ORSERDU to learn more.

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# Stemline ARC® Offers Healthcare Professionals, Office Staff, and Patients Comprehensive Support

Getting assistance from Stemline ARC for your ORSERDU patients is simple. Download and complete the form below to get your patients started.

**Enrollment form >**



**Submit by fax:**  
1-833-329-7836



**Submit by mail:**  
Stemline ARC  
PO Box 5490  
Louisville, KY 40255

- **Checking the Rapid Start\* box** allows eligible patients to begin treatment with ORSERDU at no cost to them while they await coverage information
- **Remember to fill in the “MANDATORY FIELDS” section** by adding the diagnosis codes (ICD-10-CM code) and select whether the patient received prior endocrine therapy, is ESR1 positive, and ER+/HER2-
- **Provider signature is required** to enroll patients in the ORSERDU access programs
- **Patient/caregiver signatures are required** to provide consent to enroll in the programs



## Questions?

Connect with a Stemline ARC Patient Advocate

1-833-4-STEMLINE (1-833-478-3654)

9:00 AM to 6:00 PM ET | Monday through Friday

ER+=hormone receptor positive, ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

\*The Rapid Start program is a 15-day free product program that can be accessed through Stemline ARC via the ORSERDU enrollment form. Eligible enrolled patients will receive a 15-day 345 mg ORSERDU prescription. **Patients with certain government coverage must wait 5 days after a prior authorization (PA) is submitted to be eligible for this program.** For complete terms and conditions see ORSERDUcopy.com.

**Please see Important Safety Information on pages 17 and 18 and full Prescribing Information for ORSERDU to learn more.**

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# Once Enrolled, Stemline ARC® Can Help With Access, Reimbursement, and Financial Assistance



## Access & Reimbursement Support

Services that may assist you and your office staff, including:

- Benefits investigation and verification
- PA and medical necessity requirements (see [checklist](#) on the next page)
- Case management



## Financial Assistance Programs & Ordering

Information on:

- Financial assistance options for eligible patients\*
- Ordering information



## Resources

Available comprehensive access and reimbursement-related resources to help grant your patients access to treatment, including:



[ORSERDU Sample Letter of Medical Necessity](#)



[ORSERDU Sample Letter of Appeal](#)



## Questions?

Connect with a Stemline ARC Patient Advocate

1-833-4-STEMLINE (1-833-478-3654)

9:00 AM to 6:00 PM ET | Monday through Friday

\*In order to be eligible for the ORSERDU Co-pay Card Program, the patient must not have government-funded health insurance (eg, Medicare, Medicaid, TRICARE, or any other federal or state program), must be taking ORSERDU for an FDA-approved indication, and must confirm that they meet all of the eligibility criteria and agree to the rules set forth in the terms and conditions for the program. Patients and healthcare providers are responsible for completing and submitting enrollment forms and coverage or reimbursement documentation. Stemline Therapeutics, Inc. makes no representation or guarantee concerning coverage or reimbursement of any service or item.

Please see Important Safety Information on pages 17 and 18 and full [Prescribing Information](#) for ORSERDU to learn more.

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# Navigating PAs and Payer Denial Checklist

## Stemline ARC® May Help Educate You on the PA Process

Payers may require a PA that describes your patient's medical history and the reasons why ORSERDU has been prescribed. Various health plans have different requirements. It is important to check with your patient's health plan to ensure you are using the correct form and supplying all the required information. To avoid delays, it is important to include a Letter of Medical Necessity to support the PA submission.

## PA Checklist

### Helpful reminders for the PA process

- ✓ Confirm PA requirements and how the PA should be submitted (eg, fax or phone)
- ✓ Determine if the health plan has a specific form that must be used and if it is available online
- ✓ Check the health plan's policy for treating ER+/HER2-, ESR1-mutated advanced or metastatic breast cancer<sup>1</sup> with ORSERDU to ensure medical documentation addresses specific policy requirements
- ✓ Use the appropriate billing codes starting on [page 12](#)

**All PA forms must be completed and submitted by a patient's healthcare provider based on their clinical judgment and assessment of the patient's case**

### Letter of Medical Necessity (*some payers may require this*)

- ✓ Be specific in your request (ie, requesting approval of the PA to support the prescribed medication)
- ✓ Highlight the clinical assessments that demonstrate the patient need and that the patient meets the health plan medical policy criteria for treatment with ORSERDU
- ✓ Include a copy of the health plan medical policy, if available
- ✓ Include the physician's contact information



**ORSERDU Sample  
Letter of Medical Necessity**

### Follow-up Reminders

- ✓ Call to make sure the PA request was received
- ✓ Keep a record of your phone calls: who you talked to, when, and what was agreed to or discussed
- ✓ Document the PA approval number and duration (with written confirmation, if possible)
- ✓ Include the PA reference number on the claim form, if possible

Please see Important Safety Information on [pages 17 and 18](#) and full [Prescribing Information](#) for ORSERDU to learn more.

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# Navigating PAs and Payer Denial Checklist (cont'd)

## What Happens Next?

1

If the PA is approved, be sure to document the PA approval number/date in the patient's record and make note of the expiration date.

2

If the PA is denied, you can file an appeal. Stemline ARC® can support you and provide information about how your office can properly file this paperwork. See the checklist below for additional steps.

## PA Denial/Appeal Checklist

### Helpful reminders for the PA process

- ✓ Review the denial letter to understand the reason for the denial and note any deadlines for next steps
- ✓ Compile supporting medical information, documentation, and clinical assessments
- ✓ Submit the first appeal per the health plan's process and requirements
- ✓ If rejected, submit a second appeal that responds to the health plan's concerns, questions, or requirements
- ✓ The appeal policies of many health plans allow up to 2 levels of internal appeal for PA denials
- ✓ You may have the right to request an external appeal, which can include a review by an independent expert not affiliated with the health plan or an external review board. Be sure to note any deadlines for these additional appeals



ORSERDU Sample  
Letter of Appeal

Please see Important Safety Information on pages 17 and 18 and full [Prescribing Information](#) for ORSERDU to learn more.

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# Stemline ARC® Is Committed to Patients With Their ORSERDU Treatment Journey

There are 2 points of contact for your patient:

1

## Stemline ARC Nurse Navigator\*

- Provides support and access information for ORSERDU
- Helps set expectations when taking ORSERDU (ie, storage and handling, administration)
- Available to answer patient questions†

2

## Stemline ARC Patient Advocate\*

- Provides an overview of support services
- Confirms ORSERDU coverage and financial assistance
- Shares helpful resources
- Assists in overall case management

Stemline ARC Nurse Navigators may contact your patient to check in on the progress of their treatment journey

### Welcome call

- Introduction to Stemline ARC (ie, starter kit overview, if applicable)
- Confirmation of patient information
- Overview of patient-specific benefits, such as the Rapid Start program if a Rapid Start prescription has already been filled
- What to expect with ORSERDU treatment

### Follow-up calls

- May reach out to your patients to provide support as they begin treatment
- Answers any questions the patient may have†
- Helps set expectations when taking ORSERDU (ie, storage and handling, administration)



### Questions?

Connect with a Stemline ARC Patient Advocate

1-833-4-STEMLINE (1-833-478-3654)

9:00 AM to 6:00 PM ET | Monday through Friday

\*Stemline ARC Nurse Navigators and Patient Advocates are available to provide resource information and answer questions about financial assistance, insurance benefits, and coverage for ORSERDU.

†This supplemental support is not intended to replace discussions between patients and their healthcare providers.

Please see Important Safety Information on pages 17 and 18 and full Prescribing Information for ORSERDU to learn more.

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# ORSERDU Access Programs Offer Support for Eligible Patients

Once your patients have been enrolled in **Stemline ARC®** and the benefits verification process has been completed, your Stemline ARC Patient Advocate will let your patient know what **financial support alternatives are available to them based on their eligibility.**



## ORSERDU Rapid Start Program\*

Eligible patients waiting on a PA or medical necessity approval may be able to begin treatment with ORSERDU at **no cost to them.**

**This program provides patients with a 15-day supply of ORSERDU 345 mg at no cost to them**

- Eligible patients can access this program by signing up for the **Stemline ARC services** via the **ORSERDU enrollment form** at your office
- Patients with government coverage must wait 5 days after a PA is submitted to be eligible for the program
- When submitting the **ORSERDU enrollment form**, remember to **check off the Rapid Start Program** at the top of the form and fill out the **Rapid Start Prescription in Section 5**

**Page 1**

**Page 3**

\*The Rapid Start program is a 15-day free product program that can be accessed through Stemline ARC via the ORSERDU enrollment form. Eligible enrolled patients will receive a 15-day 345 mg ORSERDU prescription. **Patients with certain government coverage must wait 5 days after a prior authorization (PA) is submitted to be eligible for this program.** For complete terms and conditions see [ORSERDUcopy.com](https://www.orserdupatients.com).

Please see Important Safety Information on pages 17 and 18 and full Prescribing Information for ORSERDU to learn more.

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# ORSERDU Access Programs Offer Support for Eligible Patients (cont'd)



## ORSERDU Co-pay Card\*

Eligible, commercial patients could **pay as little as \$0** for their medication

### Two ways for patients to get the ORSERDU Co-pay Card

Scan the QR code



OR

Visit



[ORSERDUcopay.com](https://ORSERDUcopay.com)

Once on the site, patients can get the card by answering a few questions and providing some basic information.

**For more information on the ORSERDU Co-pay Card visit [ORSERDUcopay.com](https://ORSERDUcopay.com)**



## ORSERDU Patient Assistance Program†

Eligible, uninsured, or functionally uninsured patients may be able to access their medication **at no cost**

\*Limitations apply. This offer is only available to eligible patients with private insurance. The program is not available for patients who are enrolled in Medicare, Medicaid, or any other federal or state healthcare program. Stemline Therapeutics, Inc. reserves the right to rescind, revoke, or amend this program without notice. For full eligibility criteria, and terms and conditions visit [ORSERDUcopay.com](https://ORSERDUcopay.com) or call 1-800-519-2140.

†To be eligible for this program, insured patients must have exhausted all other forms of patient assistance and meet financial criteria. Insured and uninsured patients must also meet certain eligibility criteria.

Please see Important Safety Information on pages 17 and 18 and full [Prescribing Information](#) for ORSERDU to learn more.

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# ORSERDU Ordering and Distribution

## ORSERDU Product Information<sup>1</sup>

Dose: 345 mg | NDC: 72187-0102-03

Dose: 86 mg | NDC: 72187-0101-03



ORSERDU is filled through specialty pharmacies (SPs) and specialty distributors (SDs) in the Stemline ARC<sup>®</sup> network.

## Specialty Pharmacies

### Biologics by McKesson

Phone: 1-800-850-4306

Fax: 1-800-823-4506

Website: <https://biologics.mckesson.com>

### Onco360

Phone: 1-877-662-6633

Fax: 1-877-662-6355

Website: <https://onco360.com/how-to-order/overview/>

## Specialty Distributors

### AmerisourceBergen Oncology Supply

Phone: 1-800-633-7555

Fax: 1-800-248-8205

Email: [service@oncologysupply.com](mailto:service@oncologysupply.com)

### Cardinal Health Specialty Distribution

Phone: 1-800-926-3161

Fax: 1-866-633-7005

Portal: [specialtyonline.cardinalhealth.com](https://specialtyonline.cardinalhealth.com)

Email: [gmb-b-cs-ind@cardinalhealth.com](mailto:gmb-b-cs-ind@cardinalhealth.com)

### McKesson Specialty Health

Phone: 1-800-482-6700

Fax: 1-800-289-9285

Email: [OncologyCustomerSupport@McKesson.com](mailto:OncologyCustomerSupport@McKesson.com)

NDC=National Drug Code.

Please see Important Safety Information  
on pages 17 and 18 and full Prescribing Information  
for ORSERDU to learn more.

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# ORSERDU Billing and Coding

The tables below provide examples of codes that may be required for reimbursement for ORSERDU. Please note, the use of the following codes does not guarantee payment for coverage for any product or service. Please contact the payer or Stemline ARC® at 1-833-4-STEMLINE (1-833-478-3654), Monday to Friday, 9:00 AM to 6:00 PM ET for additional coding information.

## National Drug Code (NDC) 11-digit<sup>1</sup>

Administration method	Dosage*	NDC 11-digit	Description
Oral	345 mg	72187-0102-03	Bottle of 30 tablets light blue; oval
Oral	86 mg	72187-0101-03	Bottle of 30 tablets light blue; round

## International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes<sup>2</sup>

ICD-10-CM codes	Description
Malignant neoplasm of breast	
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.11	Malignant neoplasm of central portion of breast, female
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast

\*In the EMERALD trial, the 400-mg dose of elacestrant dihydrochloride that was used contained approximately 345 mg of elacestrant free base.<sup>1</sup>

Please see Important Safety Information on pages 17 and 18 and full Prescribing Information for ORSERDU to learn more.

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# ORSERDU Billing and Coding (cont'd)

## ICD-10-CM diagnosis codes (cont'd)<sup>2</sup>

ICD-10-CM codes	Description
Malignant neoplasm of breast (cont'd)	
<b>C50.122</b>	Malignant neoplasm of central portion of left male breast
<b>C50.129</b>	Malignant neoplasm of central portion of unspecified male breast
<b>C50.21</b>	Malignant neoplasm of upper-inner quadrant of breast, female
<b>C50.211</b>	Malignant neoplasm of upper-inner quadrant of right female breast
<b>C50.212</b>	Malignant neoplasm of upper-inner quadrant of left female breast
<b>C50.219</b>	Malignant neoplasm of upper-inner quadrant of unspecified female breast
<b>C50.221</b>	Malignant neoplasm of upper-inner quadrant of right male breast
<b>C50.222</b>	Malignant neoplasm of upper-inner quadrant of left male breast
<b>C50.229</b>	Malignant neoplasm of upper-inner quadrant of unspecified male breast
<b>C50.31</b>	Malignant neoplasm of lower-inner quadrant of breast, female
<b>C50.311</b>	Malignant neoplasm of lower-inner quadrant of right female breast
<b>C50.312</b>	Malignant neoplasm of lower-inner quadrant of left female breast
<b>C50.319</b>	Malignant neoplasm of lower-inner quadrant of unspecified female breast
<b>C50.321</b>	Malignant neoplasm of lower-inner quadrant of right male breast
<b>C50.322</b>	Malignant neoplasm of lower-inner quadrant of left male breast
<b>C50.329</b>	Malignant neoplasm of lower-inner quadrant of unspecified male breast
<b>C50.41</b>	Malignant neoplasm of upper-outer quadrant of breast, female
<b>C50.411</b>	Malignant neoplasm of upper-outer quadrant of right female breast
<b>C50.412</b>	Malignant neoplasm of upper-outer quadrant of left female breast
<b>C50.419</b>	Malignant neoplasm of upper-outer quadrant of unspecified female breast
<b>C50.421</b>	Malignant neoplasm of upper-outer quadrant of right male breast
<b>C50.422</b>	Malignant neoplasm of upper-outer quadrant of left male breast
<b>C50.429</b>	Malignant neoplasm of upper-outer quadrant of unspecified male breast

Please see Important Safety Information  
on pages 17 and 18 and full [Prescribing Information](#)  
for ORSERDU to learn more.

# ORSERDU Billing and Coding (cont'd)

## ICD-10-CM diagnosis codes (cont'd)<sup>2</sup>

ICD-10-CM codes	Description
<b>Malignant neoplasm of breast (cont'd)</b>	
<b>C50.51</b>	Malignant neoplasm of lower-outer quadrant of breast, female
<b>C50.511</b>	Malignant neoplasm of lower-outer quadrant of right female breast
<b>C50.512</b>	Malignant neoplasm of lower-outer quadrant of left female breast
<b>C50.519</b>	Malignant neoplasm of lower-outer quadrant of unspecified female breast
<b>C50.521</b>	Malignant neoplasm of lower-outer quadrant of right male breast
<b>C50.522</b>	Malignant neoplasm of lower-outer quadrant of left male breast
<b>C50.529</b>	Malignant neoplasm of lower-outer quadrant of unspecified male breast
<b>C50.61</b>	Malignant neoplasm of axillary tail of breast, female
<b>C50.611</b>	Malignant neoplasm of axillary tail of right female breast
<b>C50.612</b>	Malignant neoplasm of axillary tail of left female breast
<b>C50.619</b>	Malignant neoplasm of axillary tail of unspecified female breast
<b>C50.62</b>	Malignant neoplasm of axillary tail of breast, male
<b>C50.621</b>	Malignant neoplasm of axillary tail of right male breast
<b>C50.622</b>	Malignant neoplasm of axillary tail of left male breast
<b>C50.629</b>	Malignant neoplasm of axillary tail of unspecified male breast
<b>C50.81</b>	Malignant neoplasm of overlapping sites of breast, female
<b>C50.811</b>	Malignant neoplasm of overlapping sites of right female breast
<b>C50.812</b>	Malignant neoplasm of overlapping sites of left female breast
<b>C50.819</b>	Malignant neoplasm of overlapping sites of unspecified female breast
<b>C50.821</b>	Malignant neoplasm of overlapping sites of right male breast
<b>C50.822</b>	Malignant neoplasm of overlapping sites of left male breast
<b>C50.829</b>	Malignant neoplasm of overlapping sites of unspecified male breast
<b>C50.91</b>	Malignant neoplasm of breast of unspecified site, female

Please see Important Safety Information  
on pages 17 and 18 and full [Prescribing Information](#)  
for ORSERDU to learn more.

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# ORSERDU Billing and Coding (cont'd)

## ICD-10-CM diagnosis codes (cont'd)<sup>2</sup>

ICD-10-CM codes	Description
<b>Malignant neoplasm of breast (cont'd)</b>	
<b>C50.911</b>	Malignant neoplasm of unspecified site of right female breast
<b>C50.912</b>	Malignant neoplasm of unspecified site of left female breast
<b>C50.919</b>	Malignant neoplasm of unspecified site of unspecified female breast
<b>C50.921</b>	Malignant neoplasm of unspecified site of right male breast
<b>C50.922</b>	Malignant neoplasm of unspecified site of left male breast
<b>C50.929</b>	Malignant neoplasm of unspecified site of unspecified male breast
<b>Z85.3</b>	Personal history of malignant neoplasm of breast
<b>Metastasis to bone and bone marrow</b>	
<b>C79.51</b>	Secondary malignant neoplasm of bone
<b>C79.52</b>	Secondary malignant neoplasm of bone marrow
<b>Metastasis to lung and pleura</b>	
<b>C78.00</b>	Secondary malignant neoplasm of unspecified lung
<b>C78.01</b>	Secondary malignant neoplasm of right lung
<b>C78.02</b>	Secondary malignant neoplasm of left lung
<b>C78.1</b>	Secondary malignant neoplasm of mediastinum
<b>C78.2</b>	Secondary malignant neoplasm of pleura
<b>C78.30</b>	Secondary malignant neoplasm of unspecified respiratory organ
<b>C78.39</b>	Secondary malignant neoplasm of other respiratory organs

Please see Important Safety Information  
on pages 17 and 18 and full [Prescribing Information](#)  
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# ORSERDU Billing and Coding (cont'd)

## ICD-10-CM diagnosis codes (cont'd)<sup>2</sup>

ICD-10-CM codes	Description
<b>Metastasis to lymph nodes</b>	
<b>C77.0</b>	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck
<b>C77.1</b>	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes
<b>C77.2</b>	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
<b>C77.3</b>	Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes
<b>C77.4</b>	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes
<b>C77.5</b>	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes
<b>C77.8</b>	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
<b>C77.9</b>	Secondary and unspecified malignant neoplasm of lymph node, unspecified
<b>Metastasis to liver</b>	
<b>C78.7</b>	Secondary malignant neoplasm of liver and intrahepatic bile duct
<b>Metastasis to brain</b>	
<b>C79.31</b>	Secondary malignant neoplasm of brain
<b>C79.32</b>	Secondary malignant neoplasm of cerebral meninges

Please see Important Safety Information on pages 17 and 18 and full [Prescribing Information](#) for ORSERDU to learn more.





# Important Safety Information for ORSERDU

## INDICATION

ORSERDU (elacestrant) 345 mg tablets are indicated for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

## IMPORTANT SAFETY INFORMATION

### Warnings and Precautions

- **Dyslipidemia:** Hypercholesterolemia and hypertriglyceridemia occurred in patients taking ORSERDU at an incidence of 30% and 27%, respectively. The incidence of Grade 3 and 4 hypercholesterolemia and hypertriglyceridemia were 0.9% and 2.2%, respectively. Monitor lipid profile prior to starting and periodically while taking ORSERDU.
- **Embryo-Fetal Toxicity:** Based on findings in animals and its mechanism of action, ORSERDU can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ORSERDU and for 1 week after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ORSERDU and for 1 week after the last dose.

### Adverse Reactions

- **Serious adverse reactions** occurred in 12% of patients who received ORSERDU. Serious adverse reactions in >1% of patients who received ORSERDU were musculoskeletal pain (1.7%) and nausea (1.3%). Fatal adverse reactions occurred in 1.7% of patients who received ORSERDU, including cardiac arrest, septic shock, diverticulitis, and unknown cause (one patient each).
- **The most common adverse reactions** ( $\geq 10\%$ ), including laboratory abnormalities, of ORSERDU were musculoskeletal pain (41%), nausea (35%), increased cholesterol (30%), increased AST (29%), increased triglycerides (27%), fatigue (26%), decreased hemoglobin (26%), vomiting (19%), increased ALT (17%), decreased sodium (16%), increased creatinine (16%), decreased appetite (15%), diarrhea (13%), headache (12%), constipation (12%), abdominal pain (11%), hot flush (11%), and dyspepsia (10%).

### Drug Interactions

- **Concomitant use with CYP3A4 inducers and/or inhibitors:** Avoid concomitant use of strong or moderate CYP3A4 inhibitors with ORSERDU. Avoid concomitant use of strong or moderate CYP3A4 inducers with ORSERDU.

Please see additional Important Safety Information on [page 18](#) and full [Prescribing Information](#) for ORSERDU to learn more.

# Important Safety Information for ORSERDU (cont'd)

## Use in Specific Populations

- **Lactation:** Advise lactating women to not breastfeed during treatment with ORSERDU and for 1 week after the last dose.
- **Hepatic Impairment:** Avoid use of ORSERDU in patients with severe hepatic impairment (Child-Pugh C). Reduce the dose of ORSERDU in patients with moderate hepatic impairment (Child-Pugh B).

The safety and effectiveness of ORSERDU in pediatric patients have not been established.

To report SUSPECTED ADVERSE REACTIONS, contact Stemline Therapeutics, Inc. at 1-877-332-7961 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please see full [Prescribing Information](#) for ORSERDU to learn more.

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**References:** 1. ORSERDU [prescribing information]. New York, NY: Menarini Stemline, Inc.; 2023. 2. Centers for Medicare & Medicaid Services. 2023 ICD-10-CM. Accessed February 9, 2023. <https://www.cms.gov/medicare/icd-10/2023-icd-10-cm>



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