ORSERDU®
elacestrant

# Access, Distribution, and Reimbursement Guide

## INDICATION

ORSERDU (elacestrant) 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.

## 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 accompanying full Prescribing Information.**

# Contents







# ORSERDU Product Information

## Indication[1]

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 (*ESR1*m) advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

## Dosing and Administration[1]

Select patients for treatment of ER-positive, HER2-negative advanced or metastatic breast cancer with ORSERDU based on the presence of *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 at approximately 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[1]

- Some situations may require dose interruption, adjustment, and/or discontinuation. For information on dose modifications, please see the full **Prescribing Information**

## Storage[1]

- 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 accompanying full Prescribing Information.**

ORSERDU® elacestrant

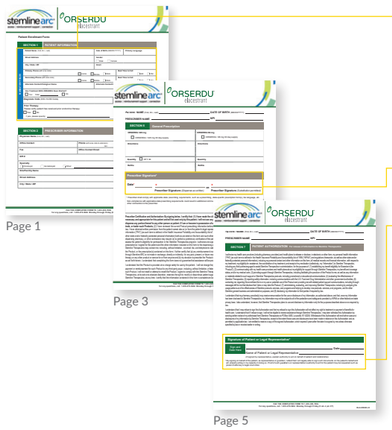
# Stemline ARC® Offers Healthcare Professionals, Office Staff, and Patients Comprehensive Support

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

## Send your completed form via:

**Fax:**
1-833-329-7836

**Mail:**
Stemline ARC
PO Box 5490
Louisville, KY 40255




- **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*m positive, and ER+/HER2-
- **Prescriber 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+=estrogen receptor positive, ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

**Please see additional Important Safety Information on pages 17 and 18 and accompanying full Prescribing Information.**



# 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 **page 6**)
- 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
- To download a copy of the resources listed above, please visit StemlineARC.com

*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.

# 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*m advanced or metastatic breast cancer[1] 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

**Download the ORSERDU Sample Letter of Medical Necessity at StemlineARC.com**

### 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



# 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

**Download the ORSERDU Sample Letter of Appeal at StemlineARC.com**

ORSERDU® elacestrant

# 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 some frequently asked 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
- 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)

stemline arc®
access | reimbursement support | connection

**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 additional Important Safety Information on pages 17 and 18 and accompanying full Prescribing Information.**



# 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 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**

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**

## 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 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.

ORSERDU® elacestrant





Scanning the QR code will hyperlink to Stemline Savings: https://stemlinesavings.com

ORSERDU Access Programs

# A Guide to Process a Prescription for ORSERDU

## E-prescribe

**Biologics by McKesson** or NPI# 1487640314
**Oncomed Dba Onco360** or NPI# 1679618151

Consider contacting your EMR representative if Biologics and/or Onco360 are not currently included in your system.

## Call the Rx into a specialty pharmacy

**Biologics Phone:** 1-800-850-4306
**Onco360 Phone:** 1-877-662-6633

## Fax the Rx to a specialty pharmacy

**Biologics Fax:** 1-800-823-4506
**Onco360 Fax:** 1-877-662-6355

**Be sure the Rx includes:**
- Start date
- Dosing instructions (include total dosage, quantity, refills)

**Patient information:**
- Date of birth
- Phone number
- Diagnosis (ICD-10-CM code and stage of disease)

**Additional tips:**
- Include front and back of patient's insurance card, including pharmacy benefit
- Add clinical information that supports the treatment decision (including pathology, lab reports, treatment history, description of the treatment plan)

## Complete and fax the specialty pharmacy referral form

**Biologics Order Form**
Scan the QR code or visit https://biologics.mckesson.com/

Scanning the QR code will hyperlink to Biologics Order Form: https://biologics.mckesson.com/wp-content/uploads/2020/05/Biologics-by-McKesson-Referral-Form.pdf

**Onco360 Order Form**
Scan the QR code or visit https://onco360.com

Scanning the QR code will hyperlink to Onco360 Order Form: https://onco360.com/how-to-order/order-forms/

## Complete and fax the ORSERDU Enrollment Form

**Stemline ARC® Fax:** 1-833-329-7836
Scan the QR code or visit StemlineARC.com

Scanning the QR code will hyperlink to the Stemline Enrollment Form: https://stemlinearc.com/pdf/ORSERDU_Stemline_ARC_Enrollment_Form.pdf

ORSERDU Prescription Processing

**A reminder that Biologics and Onco360 may call the prescriber's office to support your efforts with payer approval.**
**Staff should also remind their patients to expect calls from Biologics and Onco360 to arrange delivery and support their care.**

EMR=electronic medical record.

Please see additional Important Safety Information on pages 17 and 18 and accompanying full Prescribing Information.



ORSERDU® elacestrant

# 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 through Friday, 9:00 AM to 6:00 PM ET** for additional coding information.

## National Drug Code (NDC) 11-digit[1]

| 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[2]

| 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 hydrochloride that was used contained approximately 345 mg of elacestrant free base.[1]

Please see additional Important Safety Information on pages 17 and 18 and accompanying full Prescribing Information.



# ORSERDU Billing and Coding (cont'd)

## ICD-10-CM diagnosis codes (cont'd)[2]

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



ORSERDU® elacestrant

# ORSERDU Billing and Coding (cont'd)

## ICD-10-CM diagnosis codes (cont'd)[2]

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





Please see additional Important Safety Information
on pages 17 and 18 and accompanying full Prescribing Information.

# ORSERDU Billing and Coding (cont'd)

## ICD-10-CM diagnosis codes (cont'd)[2]

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

# ORSERDU Billing and Coding (cont'd)

## ICD-10-CM diagnosis codes (cont'd)[2]

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



Please see additional Important Safety Information on pages 17 and 18 and accompanying full Prescribing Information.

# Important Safety Information for ORSERDU

## INDICATION

ORSERDU (elacestrant) 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.

## 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** (≥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.

See next page for additional Important Safety Information.

ORSERDU® elacestrant

# 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.

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

**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.**

**Please see accompanying full Prescribing Information, including Patient Information.**

# Notes

*The information contained in the guide is intended to provide a general understanding of the coding and billing process and is not intended to assist healthcare professionals in obtaining reimbursement for any specific claim. The guide is for informational purposes only and does not represent legal or billing advice. The content here is based on information as of December 20, 2023, and is subject to change.*

**References: 1**. ORSERDU [prescribing information]. New York, NY: Menarini Stemline, Inc.; 2023. **2.** Centers for Medicare & Medicaid Services. 2024 ICD-10-CM. Accessed December 20, 2023. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm

stemline arc®
access | reimbursement support | connection

ORSERDU®
elacestrant