

# ORSERDU®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

## 1. Why am I taking ORSERDU?

ORSERDU contains the active ingredient elacestrant dihydrochloride. ORSERDU is used to treat postmenopausal women and men with a specific type of breast cancer that is advanced or has spread to other parts of the body. It can be used to treat estrogen receptor (ER)-positive and human epidermal growth factor receptor 2 (HER2)-negative breast cancer in patients who have certain mutations in a gene called *ESR1*. It is used as monotherapy in patients whose cancer has not responded to or progressed further following at least one line of hormonal treatment including a CDK 4/6 inhibitor. For more information, see Section [1. Why am I taking ORSERDU?](#) in the full CMI.

## 2. What should I know before I take ORSERDU?

Do not take if you have ever had an allergic reaction to elacestrant dihydrochloride or any of the ingredients listed at the end of the full CMI. Talk to your doctor if you have any liver disease, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I take ORSERDU?](#) in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with ORSERDU and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

## 4. How do I take ORSERDU?

- Your doctor will tell you exactly how many tablets to take. Check with your doctor or pharmacist if you are not sure.
- ORSERDU may be taken with food to reduce nausea and vomiting. Avoid grapefruit or grapefruit juice during treatment with ORSERDU. ORSERDU tablets should be swallowed whole. They should not be chewed, crushed or split prior to swallowing.

More instructions can be found in Section [4. How do I take ORSERDU?](#) in the full CMI.

## 5. What should I know while taking ORSERDU?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● Remind any doctor, dentist or pharmacist you visit that you are taking ORSERDU.</li><li>● Use effective contraception to avoid becoming pregnant during treatment with ORSERDU and for one week after stopping treatment with ORSERDU.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>● Do not stop taking ORSERDU without talking to your doctor or pharmacist because your condition may worsen.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>● Be careful before you drive or use any machinery until you know how ORSERDU affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>● Keep your tablets in the blister pack until it is time to take them. Store</li></ul>

your medicine in a cool dry place below 30°C. Keep your medicine where children cannot reach it.

For more information, see Section [5. What should I know while taking ORSERDU?](#) in the full CMI.

## **6. Are there any side effects?**

Like all medicines, ORSERDU can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment.

Serious potential side effects requiring medical attention include liver failure (acute hepatic failure) and blood clots (venous thromboembolism).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

## **ORSERDU®** (or-SER-doo)

**Active ingredient:** *elacestrant dihydrochloride*

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### **Consumer Medicine Information (CMI)**

This leaflet provides important information about taking ORSERDU. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking ORSERDU.**

#### **Where to find information in this leaflet:**

- [1. Why am I taking ORSERDU?](#)
- [2. What should I know before I take ORSERDU?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take ORSERDU?](#)
- [5. What should I know while taking ORSERDU?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking ORSERDU?

**ORSERDU contains the active ingredient elacestrant (as dihydrochloride).**

ORSERDU is a selective estrogen receptor degrader that binds to the oestrogen receptors in the cancer cells and stops them from working. By blocking and destroying estrogen receptors, ORSERDU can reduce the growth and spread of breast cancer and help to kill cancer cells.

ORSERDU is used to treat postmenopausal women and adult men who have a specific type of breast cancer that is advanced or has spread to other parts of the body (metastatic). It can be used to treat breast cancer that is estrogen receptor (ER)-positive, meaning that the cancer cells have receptors for the hormone oestrogen on their surface, and that is human epidermal growth factor receptor 2 (HER2)-negative, meaning that cancer cells have no or only a small amount of this receptor on their surface. ORSERDU is used as monotherapy (used on its own) in patients whose cancer has not responded to or progressed further following at least one line of hormonal treatment including a CDK 4/6 inhibitor and who have certain changes (mutations) in a gene called *ESR1*.

Your doctor will take a sample of your blood, which will be tested for these *ESR1* mutations. A positive result is required for initiation of treatment with ORSERDU.

## 2. What should I know before I take ORSERDU?

### Warnings

#### Do not take ORSERDU if:

- you are allergic to elacestrant dihydrochloride, or any of the ingredients listed at the end of this leaflet.

#### Check with your doctor if you:

- have a liver disease (examples of liver disease include cirrhosis (scarring of the liver), liver impairment or cholestatic jaundice (yellowing of the skin and eyes due to a reduced flow of bile from the liver)). Your doctor will monitor you regularly and closely for adverse reactions.
- have an increased risk of developing blood clots in your veins (a type of blood vessel). By having advanced breast cancer, you may have an increased risk of developing blood clots in your veins. It is unknown if ORSERDU also increases this risk.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Children and adolescents**

ORSERDU is not to be used in children and adolescents under 18 years of age.

## **Pregnancy, breastfeeding and fertility**

This medicine should only be used in postmenopausal women and in men.

- ORSERDU can cause harm to an unborn baby. You must not take ORSERDU if you are pregnant, think you may be pregnant or are planning to have a baby. If you think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.
- If you are a woman who could become pregnant, you should use effective contraception while you are being treated with ORSERDU and for one week after stopping treatment with ORSERDU. Ask your doctor for suitable methods. If you are a woman who could become pregnant, your doctor will rule out an existing pregnancy before starting you on treatment with ORSERDU. This may include having a pregnancy test.
- You must not breast-feed while on treatment with ORSERDU and for one week after the last dose of ORSERDU. During treatment, your doctor will discuss the potential risks of taking ORSERDU during pregnancy or breast-feeding.
- ORSERDU may impair fertility in women and men.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

The effects of ORSERDU may be influenced if you take ORSERDU together with any of the following medicines, food or drinks:

- antibiotics to treat bacterial infections (such as ciprofloxacin, clarithromycin, erythromycin or rifampicin)
- medicines to treat depression (such as fluvoxamine)
- medicines for the treatment of other cancers (such as crizotinib, dabrafenib, imatinib, lorlatinib, or sotorasib)
- medicines for high blood pressure or chest pain (such as bosentan, diltiazem or verapamil)
- medicines for fungal infections (such as fluconazole, isavuconazole, itraconazole, ketoconazole, posaconazole, or voriconazole)
- medicines for HIV infection (such as efavirenz, etravirine, lopinavir or ritonavir)
- medicines to treat irregular heartbeats (such as digoxin)
- medicines used in organ transplantation to prevent rejection (such as ciclosporin)
- medicines to prevent cardiovascular events and to treat high levels of cholesterol (such as rosuvastatin)

- medicines used to prevent seizures (such as carbamazepine, phenobarbital, phenytoin, or primidone)
- medicines to treat vomiting (such as aprepitant)
- herbal medicines used to treat depression containing St. John's wort
- grapefruit or grapefruit juice

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ORSERDU.**

## **4. How do I take ORSERDU?**

### **How much ORSERDU to take**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of ORSERDU is 345 mg (one 345 mg film coated tablet) once daily. Your doctor will tell you exactly how many tablets to take. In certain situations (i.e. in case of liver problems, side effects, or if you are also using certain other medicines your doctor may instruct you to take a lower dose of ORSERDU, e.g. 258 mg (3 tablets of 86 mg) once daily, 172 mg (2 tablets of 86 mg) once daily, or 86 mg (1 tablet of 86 mg) once daily.

ORSERDU should be taken with food, just avoid grapefruit and grapefruit juice during treatment with ORSERDU (see Section [3. What if I am taking other](#)

[medicines?](#)). Taking ORSERDU with food may reduce nausea and vomiting.

ORSERDU tablets should be swallowed whole. They should not be chewed, crushed or split prior to swallowing. Do not take a tablet that is broken, cracked or otherwise damaged.

## **If you forget to take ORSERDU**

Take your dose of ORSERDU at approximately the same time each day. This will help you to remember to take your medicine.

If you forget to take a dose of ORSERDU, take it as soon as you remember. You may still take a forgotten dose up to 6 hours after the time you should have taken it.

If more than 6 hours have passed or if you vomit after taking the dose, skip the dose for that day and take the next dose at your usual time the next day.

Do not take a double dose to make up for the one that you missed.

## **If you take more ORSERDU than you should**

You may be more likely to experience the side effects listed in Section [6. Are there any side effects?](#) or you may experience the gut and digestion related side effects more severely. If you think that you have taken too much ORSERDU, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor or pharmacist, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while taking ORSERDU?**

### **Things you should do**

- Tell any other doctors, dentists and pharmacists who are treating you that you are taking ORSERDU, including when you are to be started on a new medicine.
- Keep your appointments with your doctor so your progress is monitored.
- Use effective contraception while you are being treated with ORSERDU and for one week after stopping treatment with ORSERDU to avoid becoming pregnant.

### **Things you should not do**

- Do not stop taking ORSERDU without talking to your doctor or pharmacist. If treatment with ORSERDU is stopped, your condition may worsen.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how ORSERDU affects you.**

ORSERDU has no or negligible influence on the ability to drive and use machines. However, since fatigue, weakness, and difficulty sleeping have been reported in some patients taking ORSERDU, caution should be observed by patients who experience those adverse reactions when driving or operating machinery.

## **Looking after your medicine**

Store it in a cool dry place, below 30°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>Blood tests:</b></p> <ul style="list-style-type: none"><li>• Some blood tests may be abnormal (Increased level of triglycerides, cholesterol, creatinine, alanine aminotransferase, and aspartate aminotransferase, and alkaline phosphatase in your blood. Decreased level of calcium, sodium, red blood cells, lymphocytes, and potassium in your blood)</li></ul> <p><b>Gastrointestinal issues:</b></p> <ul style="list-style-type: none"><li>• Feeling sick (nausea)</li><li>• Vomiting</li><li>• Diarrhoea</li><li>• Constipation</li><li>• Abdominal pain</li><li>• Indigestion (dyspepsia)</li></ul>	<p><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Decreased appetite</li> <li>● Inflammation of the mouth and lips (stomatitis)</li> </ul> <p><b>General disorders:</b></p> <ul style="list-style-type: none"> <li>● Tiredness (fatigue)</li> <li>● Headache</li> <li>● Back pain</li> <li>● Joint pain (arthralgia)</li> <li>● Hot flushes</li> <li>● Weakness (asthenia)</li> <li>● Fainting (syncope)</li> <li>● Dizziness</li> <li>● Difficulty falling and staying asleep (insomnia)</li> <li>● Pain in hands or legs (pain in extremity)</li> <li>● Bone pain</li> <li>● Chest pain relating to the muscles and bones in the chest (Musculoskeletal chest pain)</li> </ul> <p><b>Infection issues:</b></p> <ul style="list-style-type: none"> <li>● Infection of the parts of the body that collect and</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<p>pass out urine (urinary tract infection)</p> <p><b>Respiratory:</b></p> <ul style="list-style-type: none"> <li>• Cough</li> <li>• Shortness of breath (dyspnoea)</li> </ul> <p><b>Skin reactions:</b></p> <ul style="list-style-type: none"> <li>• Rash</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Blood clots (venous thromboembolism). Signs and symptoms include: <ul style="list-style-type: none"> <li>○ feelings of warmth, swelling, tenderness, cramping and/ or pain of a limb (usually one leg)</li> <li>○ sudden shortness of breath, chest pain, increased heart rate and/or coughing up blood</li> </ul> </li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Liver failure (acute hepatic failure). Signs and symptoms include:               <ul style="list-style-type: none"> <li>○ sudden yellowing of the eyes/skin</li> <li>○ sudden tenderness in the upper abdomen</li> <li>○ changes in mental state or behaviour</li> </ul> </li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What ORSERDU contains

<b>Active ingredient (main ingredient)</b>	Elacestrant dihydrochloride
<b>Other ingredients (inactive ingredients)</b>	Microcrystalline cellulose, silicified microcrystalline cellulose, crospovidone, magnesium stearate, silica amorphous and Opadry II 85F105080 Blue (polyvinyl alcohol, titanium dioxide, macrogol 3350, purified talc and Brilliant Blue FCF Aluminium Lake)

**Do not take this medicine if you are allergic to any of these ingredients.**

### What ORSERDU looks like

ORSERDU is supplied as film coated tablets in aluminium blisters.

ORSERDU 86 mg is a blue to light blue, biconvex round shaped film coated tablet with “ME” debossed on one side and plain face on the opposite side. Approximate diameter: 8.8 mm. (AUST R 437531)

ORSERDU 345 mg is a blue to light blue, biconvex, oval shaped film coated tablet with “MH” debossed on one side and plain face on the opposite side. Approximate size: 19.2 mm (length), 10.8 mm (width). (AUST R 437532)

Each pack contains 28 film coated tablets (4 blisters with 7 tablets each).

## **Who distributes ORSERDU**

A. Menarini Australia Pty Ltd

Sydney, Australia

Tel: 1800 644 542

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