

ORSERDU FILM-COATED TABLETS

Elacestrant (86mg, 345mg)

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What ORSERDU is used for

This medicine 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.

How ORSERDU works

Oestrogen receptors are a group of proteins found inside the cells. They are activated when the hormone oestrogen binds to them. By binding to these receptors, oestrogen can in some cases stimulate cancer cells to grow and multiply. ORSERDU contains the active substance elacestrant that binds to the oestrogen receptors in the cancer cells and stops them from working. By blocking and destroying oestrogen receptors, ORSERDU can reduce the

growth and spread of breast cancer and help to kill cancer cells.

If you have any questions about how ORSERDU works or why this medicine has been prescribed for you, ask your doctor, pharmacist, or nurse.

Before you use ORSERDU

- When you must not use it

Do not use ORSERDU if you are allergic to elacestrant or any of the other ingredients of this medicine (listed in Product Description).

- Before you start to use it

Talk to your doctor or pharmacist before taking ORSERDU

-if you have any 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.

By having advanced breast cancer you may have an increased risk of developing blood clots in your veins (a type of blood vessel). It is unknown if ORSERDU also increases this risk.

ORSERDU should not be given to children and adolescents under 18 years of age.

- Pregnancy and lactation

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

- Pregnancy

ORSERDU may harm 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.

- Breast-feeding

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.

- Fertility

ORSERDU may impair fertility in women and men.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because ORSERDU can affect the way some other medicines work. Also, some other medicines can affect the way ORSERDU works.

Tell your doctor if you take any of the following medicines:

- antibiotics to treat bacterial infections (such as ciprofloxacin, clarithromycin, erythromycin, rifampicin, telithromycin)
- medicine for low blood sodium (such as conivaptan)
- medicines to treat depression (such as nefazodone or fluvoxamine)
- medicine to treat anxiety and alcohol withdrawal (such as tofisopam).
- 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, indinavir, lopinavir, ritonavir, nelfinavir, saquinavir, or telaprevir)
- medicines to treat irregular heartbeats (such as digoxin, dronedarone, or quinidine)

- medicines used in organ transplantation to prevent rejection (such as cyclosporine)
- medicines to prevent cardiovascular events and to treat high levels of cholesterol (such as rosuvastatin)
- medicines used to prevent seizures (such as carbamazepine, cenobamate, phenobarbital, phenytoin, or primidone)
- medicines to treat vomiting (such as aprepitant)
- herbal medicines used to treat depression containing St. John's wort

How to use ORSERDU

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

ORSERDU should be taken with food, just avoid grapefruit and grapefruit juice during treatment with ORSERDU (See Things to be careful of). 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.

- How much to use

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.

- When to use it

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

- How long to use it

Use this medicine for the duration that your doctor recommends.

- If you forget to use it

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 use too much (overdose)

Tell your doctor or pharmacist if you think you have accidentally taken more ORSERDU than you should. He or she will decide what to do.

While you are using ORSERDU

- Things you must do

Use your medicine exactly as your doctor has told you.

- Things you must not do

Do not stop using this medicine without talking to your doctor or pharmacist. If treatment with ORSERDU is stopped, your condition may worsen. If you have any further questions on the use of this medicine, ask your doctor or pharmacist

- Things to be careful of

Do not drink grapefruit juice or eat grapefruit while on treatment with ORSERDU as it may change the amount of ORSERDU in your body and increase the side effects of ORSERDU

- Driving and using machines

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 elacestrant, caution should be observed by patients who experience those adverse reactions when driving or operating machinery.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or nurse if you notice any of the following side effects:

Very common (may affect more than 1 in 10 people)

- Decreased appetite
- Feeling sick (nausea)

- Increased triglycerides and cholesterol levels in your blood
- Vomiting
- Tiredness (fatigue)
- Indigestion (dyspepsia)
- Diarrhoea
- Decreased calcium levels in your blood
- Back pain
- Increased creatinine levels in your blood
- Joint pain (arthralgia)
- Decreased sodium levels in your blood
- Constipation
- Headache
- Hot flushes
- Abdominal pain
- Low levels of red blood cells, as measured in blood tests (anaemia)
- Decreased potassium levels in your blood
- Elevated liver function, as measured in blood tests (alanine aminotransferase increased, aspartate aminotransferase increased)

Common (may affect up to 1 in every 10 people)

- Pain in hands or legs (pain in extremity)
- Weakness (asthenia)
- Infection of the parts of the body that collect and pass out urine (urinary tract infection)
- Cough
- Shortness of breath (dyspnoea)
- Difficulty falling and staying asleep (insomnia)
- Elevated liver function, as measured in blood tests (Blood alkaline phosphatase increased)
- Rash
- Low levels of lymphocytes (a type of white blood cell), as measured in blood tests (Lymphocyte count decreased)
- Bone pain
- Dizziness
- Chest pain relating to the muscles and bones in the chest (Musculoskeletal chest pain)
- Inflammation of the mouth and lips (stomatitis)
- Fainting (syncope)

Uncommon (may affect up to 1 in every 100 people)

- Increased risk of blood clots (thromboembolism)
- Liver failure (acute hepatic failure)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of ORSERDU

- Storage

Keep out of the reach and sight of children.

Store below 30°C

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

ORSERDU is supplied as film-coated tablets in aluminium blisters.

ORSERDU 86 mg film-coated tablets: 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.

ORSERDU 345 mg film-coated tablets: 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).

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

- Ingredients

- Active ingredient(s):

- Each 86 mg Orserdu Film-coated Tablets contains 86.3 mg of elacestrant.
- Each 345 mg Orserdu Film-coated Tablets contains 345 mg of elacestrant

- Inactive ingredients:

Tablet core:

- Microcrystalline cellulose [E460]
- Silicified microcrystalline cellulose
- Crospovidone [E1202]
- Magnesium stearate [E470b]
- Colloidal silicon dioxide [E551]

Film-coating:

- Opadry II 85F105080 Blue containing polyvinyl alcohol [E1203], titanium dioxide

[E171],, macrogol [E1521], talc [E553b] and brilliant blue FCF aluminium lake [E133]

- MAL number:

ORSERDU 86 mg film-coated tablets

MAL*****

ORSERDU 345 mg film-coated tablets

MAL*****

Manufacturer

Catalent Greenville, Inc.
1240 Sugg Parkway,
Greenville, NC, 27834,
USA

Product Registration Holder

A. Menarini Singapore Pte Ltd
B-18-2, Level 18, The Ascent Paradigm,
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19/12/2025

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