Package leaflet: Information for the patient

KORSERDU 86 mg film-coated tablets
KORSERDU 345 mg film-coated tablets
elacestrant

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What KORSERDU is and what it is used for

What KORSERDU is

KORSERDU contains the active substance elacestrant which belongs to a group of medicines called selective estrogen receptor degraders.

What KORSERDU 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. KORSERDU 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 KORSERDU.

How KORSERDU 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. KORSERDU 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, KORSERDU can reduce the growth and spread of breast cancer and help to kill cancer cells.

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

2. What you need to know before you take KORSERDU

Do not use KORSERDU if:
- you are allergic to elacestrant or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking KORSERDU

- 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 KORSERDU also increases this risk.

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

Other medicines and KORSERDU
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because KORSERDU can affect the way some other medicines work. Also, some other medicines can affect the way KORSERDU 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
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KORSERDU with food and drink
Do not drink grapefruit juice or eat grapefruit while on treatment with KORSERDU as it may change the amount of KORSERDU in your body and increase the side effects of KORSERDU (see Section 3 "How to take KORSERDU").

Pregnancy, breast-feeding and fertility
This medicine should only be used in postmenopausal women and in men.

Pregnancy
KORSERDU may harm an unborn baby. You must not take KORSERDU 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 KORSERDU and for one week after stopping treatment with KORSERDU. 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 KORSERDU. This may include having a pregnancy test.

Breast-feeding
You must not breast-feed while on treatment with KORSERDU and for one week after the last dose of KORSERDU. During treatment, your doctor will discuss the potential risks of taking KORSERDU during pregnancy or breast-feeding.

Fertility
KORSERDU may impair fertility in women and men.

Driving and using machines
KORSERDU 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.

3. How to take KORSERDU

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

KORSERDU should be taken with food, just avoid grapefruit and grapefruit juice during treatment with KORSERDU (see section 2 "KORSERDU with food and drink"). Taking KORSERDU with food may reduce nausea and vomiting.

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

KORSERDU 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.

The recommended dose of KORSERDU 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 KORSERDU, 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.

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

If you forget to take KORSERDU
If you forget to take a dose of KORSERDU, 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 stop taking KORSERDU
Do not stop using this medicine without talking to your doctor or pharmacist. If treatment with KORSERDU is stopped, your condition may worsen.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible 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)

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store KORSERDU

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister pack after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice any damage to the packaging or if there are any signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What KORSERDU contains
- The active substance is elacestrant.
  * Each 86 mg KORSERDU film-coated tablet contains 86.3 mg of elacestrant.
  * Each 345 mg KORSERDU film-coated tablet contains 345 mg of elacestrant

* The other ingredients are:

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])

What KORSERDU looks like and contents of the pack
KORSERDU is supplied as film-coated tablets in aluminium blisters.

KORSERDU 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.

KORSERDU 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)

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This leaflet was last revised in 05/2024