NOVARTIS

KRYXANA 200 mg

Film-coated tablets

(Ribociclib)

Patient Information Leaflet

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PATIENT INFORMATION LEAFLET

Scheduling status: S4

Kryxana 200 mg film-coated tablets

(ribociclib)

Sugar free

Read this leaflet carefully before you start taking Kryxana

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Kryxana has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Kryxana is and what it is used for
2. What you need to know before you take Kryxana
3. How to take Kryxana
4. Possible side effects
5. How to store Kryxana
6. Contents of the pack and other information

1. What Kryxana is and what it is used for

What Kryxana is

Kryxana contains the active substance ribociclib, which belongs to a group of medicines called cyclin-dependent kinase (CDK) inhibitors.

What Kryxana is used for

Kryxana is used in women or men with a type of breast cancer called hormone receptor-positive, human epidermal growth factor receptor 2-negative breast cancer that is:

- localised to the breast or could have spread to the lymph nodes in the region of the breast, with no detectable spread to other parts of the body, been surgically removed, and have certain characteristics that increase the risk of the cancer returning. It is used in combination with an aromatase inhibitor, which is used as hormonal anticancer therapies to prevent the cancer from coming back after surgery (treatment after surgery is called adjuvant therapy) (early breast cancer).

- locally advanced or has spread to other parts of the body (metastatic). It is used in combination with an aromatase inhibitor or fulvestrant, which are used as hormonal anticancer therapies (advanced or metastatic breast cancer).

Women who have not reached menopause will also be treated with a medicine called a luteinising hormone releasing hormone (LHRH) agonist.

How Kryxana works

Kryxana works by blocking proteins called cyclin-dependent kinases 4 and 6, which are important for the growth and division of cells. Blocking these proteins can slow down the growth of cancer cells and delay the progression of your cancer.

If you have any questions about how Kryxana 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 Kryxana

Follow all of your doctor's instructions carefully.

Do not take Kryxana:

- if you are allergic to ribociclib, peanut, soya or any of the other ingredients of this medicine (listed in section 6).

If you think you may be allergic, ask your doctor for advice.

- If you are pregnant or breastfeeding your baby
- If you have a difficult to control or an unstable serious heart condition such as heart failure, a recent heart attack (myocardial infarction), heart rate and/or heart rhythm problems or angina pectoris (severe chest pain due to insufficient blood flow to the heart muscle).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Kryxana.

If any of the following apply to you, tell your doctor or pharmacist before taking Kryxana:

- If you have a fever, sore throat or mouth ulcers due to infections (signs of a low level of white blood cells).
- If you have any problems with your liver or have previously had any type of liver disease.
- If you have or have had heart disorders or heart rhythm disorders, such as an irregular heartbeat, including a condition called prolonged QT syndrome (QT interval prolongation) or low levels of potassium, magnesium, calcium or phosphorus in your blood. (See "Do not take Kryxana").

If any of the following apply to you during your treatment with Kryxana, tell your doctor or pharmacist:

- If you have a combination of any of the following symptoms: rash, red skin, blistering of the lips, skin peeling, high fever, flu-like symptoms and enlarged lymph nodes (signs of a severe skin

reaction). In case of a severe skin reaction, your doctor will ask you to immediately and permanently stop treatment with Kryxana.

- Trouble breathing, cough and shortness of breath (may be signs of lung or breathing problems). If necessary, your doctor may interrupt or reduce your dose of Kryxana or decide to stop treatment with Kryxana permanently.

Monitoring during your treatment with Kryxana

You will have regular blood tests before and during treatment with Kryxana to check your liver function and the amount of blood cells (white blood cells, red blood cells and platelets) and electrolytes (blood salts including potassium, calcium, magnesium and phosphate) in your body. Your heart activity will also be monitored before and during treatment with Kryxana with a test called an electrocardiogram (ECG). If necessary, your doctor may reduce your dose of Kryxana or temporarily stop it to allow your liver, blood cells, electrolyte levels or heart activity to recover. Your doctor may also decide to stop treatment with Kryxana permanently.

Children and adolescents

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

Other medicines and Kryxana

Before you take Kryxana, tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines or supplements obtained without a prescription, because these may influence the effect of Kryxana. This includes in particular:

- Tamoxifen, another medicine for the treatment of breast cancer.
- Some medicines used to treat fungal infections, such as ketoconazole, itraconazole, voriconazole or posaconazole.

- Some medicines used to treat HIV/AIDS such as ritonavir, saquinavir, indinavir, lopinavir, nelfinavir, telaprevir and efavirenz.
- Some medicines used to treat seizures or fits (anti-epileptics) such as carbamazepine and phenytoin.
- St. John's Wort (also known as *Hypericum perforatum*) - a herbal product used to treat depression and other conditions.
- Some medicines used to treat heart rhythm problems or high blood pressure such as amiodarone, disopyramide, procainamide, quinidine, sotalol and verapamil.
- Antimalarials such as chloroquine.
- Antibiotics such as clarithromycin, telithromycin, moxifloxacin, rifampicin, ciprofloxacin, levofloxacin and azithromycin.
- Some medicines used for sedation or anaesthesia such as midazolam.
- Some medicines used as antipsychotics such as haloperidol.
- Medicines used to treat angina such as bepridil.
- Methadone, used to treat pain or addiction to opioids.
- Medicines like intravenous ondansetron, used to prevent nausea and vomiting caused by chemotherapy (treatment with cancer medicines).

Kryxana may increase or decrease your blood levels of some other medicines. This includes in particular:

- Medicines used to treat symptoms of benign prostatic hyperplasia such as alfuzosin.
- Tamoxifen, another medicine used for the treatment of breast cancer.
- Anti-dysrhythmics such as amiodarone or quinidine.
- Antipsychotics such as pimozide or quetiapine.
- Medicines used to improve blood fat levels such as simvastatin or lovastatin, pitavastatin, pravastatin or rosuvastatin.

- Medicines used to treat high blood sugar levels (e.g. diabetes) such as metformin.
- Medicines used to treat cardiac disorders such as digoxin.
- Medicines used to treat pulmonary arterial hypertension and erectile dysfunction such as sildenafil.
- Medicines used to treat low blood pressure or migraine such as ergotamine or dihydroergotamine.
- Some medicines used to treat epileptic fits or which are used for sedation or anaesthesia such as midazolam.
- Medicines used to treat sleep disorders such as triazolam.
- Analgesics such as alfentanil and fentanyl.
- Medicines used for the treatment of gastrointestinal disorders such as cisapride.
- Medicines used to prevent the rejection of an organ transplant such as tacrolimus, sirolimus and ciclosporin (also used to treat inflammation in rheumatoid arthritis and psoriasis).
- Everolimus, used for several types of cancer and tuberous sclerosis (also used to prevent the rejection of an organ transplant).

Make sure you tell your doctor of all medicines and supplements, including herbal medicines, that you are taking before you start treatment with Kryxana and if you are prescribed a new medicine after you have started treatment with Kryxana.

Ask your doctor or pharmacist if you are not sure if your medicine is one of the medicines listed above.

Kryxana with food and drink

You should not eat grapefruits or drink grapefruit juice during your treatment with Kryxana. It may change how Kryxana is processed in your body and may increase the amount of Kryxana in your bloodstream.

Pregnancy and breastfeeding

You should not be treated with Kryxana if you are pregnant or breastfeeding your baby (See "Do not take Kryxana")

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Your doctor will discuss with you the potential risks of taking Kryxana during pregnancy.

Pregnancy and women of childbearing potential

Kryxana should not be used during pregnancy since it may harm your unborn baby. If you are a woman of childbearing potential, you should have a negative pregnancy test before starting treatment with Kryxana. You should use effective contraception (e.g. double-barrier contraception such as condom and diaphragm) while taking Kryxana and for at least 21 days after the last dose. Ask your doctor about options for effective contraception.

Breastfeeding

You should not breast-feed while taking Kryxana and for at least 21 days after the last dose.

Driving and using machines

Treatment with Kryxana may lead to tiredness, dizziness or spinning sensation. You should therefore be cautious when driving or using machines during your treatment with Kryxana.

Kryxana contains soya lecithin

If you are allergic to peanut or soya, do not use this medicine.

Kryxana is sugar free.

3. How to take Kryxana

Always take Kryxana exactly as your doctor, pharmacist or nurse has told you. Your doctor, pharmacist or nurse will tell you exactly how many tablets to take and which days to take them on.

Check with your doctor, pharmacist or nurse if you are not sure. Do not change the Kryxana dose or schedule without talking to your doctor.

Do not exceed the recommended dose prescribed by your doctor.

How much Kryxana to take

- The recommended starting dose of Kryxana in early breast cancer is 400 mg (2 tablets of 200 mg). The recommended starting dose of Kryxana in advanced or metastatic breast cancer is 600 mg (3 tablets of 200 mg) once daily. Your doctor will tell you exactly how many tablets of Kryxana to take; in certain situations, your doctor may instruct you to take a lower dose of Kryxana, e.g. 400 mg (2 tablets of 200 mg) once daily or 200 mg (1 tablet of 200 mg) once daily.
- A treatment cycle lasts 28 days. Take Kryxana once a day only on days 1 to 21 of a 28-day cycle. The outer carton of the Kryxana pack includes a “calendar tool” which allows you to track your daily Kryxana dose by marking off a circle for every tablet you take over the 28-day cycle. You should not take Kryxana on days 22 to 28 of the cycle.

It is very important to follow your doctor’s instructions. If you get certain side effects, your doctor may ask you to take a lower dose, interrupt your treatment with Kryxana, or stop it permanently.

When to take Kryxana

Take Kryxana once daily at the same time each day, preferably in the morning. This will help you to remember to take your medicine.

How to take Kryxana

Kryxana tablets should be swallowed whole (tablets should not be chewed, crushed or split before swallowing). Do not take a tablet that is broken, cracked or otherwise damaged. You may take Kryxana with or without food.

How long to take Kryxana

Take Kryxana once a day on days 1 to 21 of a 28-day cycle. Continue Kryxana treatment for as long as your doctor tells you to.

This is a long-term treatment, possibly lasting for months or years. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you take more Kryxana than you should

If you take too many tablets, or if someone else takes your medicine, contact a doctor or hospital for advice immediately. Show the Kryxana packet. Medical treatment may be necessary.

If you miss a dose of Kryxana

If you vomit after taking the dose or forget a dose, skip the missed dose that day. Take the next dose at your usual time.

Do not take a double dose to make up for a missed dose. Instead, wait until it is time for your next dose and then take your usual dose.

If you stop taking Kryxana

Stopping your treatment with Kryxana may cause your condition to get worse. Do not stop taking Kryxana unless your doctor tells you to.

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

4. Possible side effects

Kryxana can cause side effects.

Not all side effects reported for Kryxana are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Kryxana, please consult your health care provider for advice.

Early breast cancer

The following side effects have been reported to be associated with Kryxana treatment of patients with early breast cancer.

Some side effects could be serious

Tell your doctor immediately if you get any of the following symptoms during treatment with Kryxana:

- Fever, sweating or chills, cough, flu-like symptoms, weight loss, shortness of breath, blood in your phlegm, sores on your body, warm or painful areas on your body, diarrhoea or stomach pain, or feeling very tired (signs or symptoms of infections)

- Fever, sore throat, or mouth ulcers due to infections (signs of low level of white blood cells)
- Abnormal results of blood tests that give information about the health of the liver (abnormal liver function tests)

Tell your doctor if you notice any of the following:

Frequent: *may affect up to 1 in every 10 people*

- Spontaneous bleeding or bruising (signs of low level of thrombocytes, also called platelets)
- Fever, sore throat, or mouth ulcers due to infections (signs of low level of lymphocytes, a type of white blood cells)
- Reduced level of potassium in the blood, which could lead to disturbances in heart rhythm (hypokalaemia)
- Irregular heartbeat (change in the electrical activity of the heart)
- Liver damage (hepatotoxicity)

Less frequent: *may affect up to 1 in every 100 people*

- Sore throat or mouth ulcers with a single episode of fever of at least 38.3 °C or fever above 38 °C for more than one hour and/or with infection (febrile neutropenia).

Other possible side effects

Other side effects include the following listed below. If these side effects become severe, tell your doctor, pharmacist, or healthcare provider.

Frequent: *may affect more than 1 in 10 people*

- Sore throat, runny nose, blocked nose, sneezing, feeling of pressure or pain in the cheeks or forehead with or without fever, cough, hoarseness, weak voice, or voice loss (symptoms of respiratory tract infections)

- Painful and frequent urination (urinary tract infection)
- Nausea
- Headache
- Tiredness (fatigue)
- Weakness (asthenia)
- Hair loss or hair thinning (alopecia)
- Diarrhoea
- Constipation
- Cough
- Abdominal pain
- Fever (pyrexia)
- Rash
- Dizziness or light headedness
- Tiredness, fatigue, pale skin (potential sign of low level of red blood cells, anaemia)
- Vomiting
- Itching (pruritus)
- Swollen hands, ankles, or feet (peripheral oedema)
- Shortness of breath, difficulty breathing (dyspnoea)
- Mouth sores or ulcers with gum inflammation (stomatitis)
- Sore throat (oropharyngeal pain)
- Reduced level of calcium in the blood, which may sometimes lead to cramps
- Reduced appetite
- Abnormal kidney blood test result (indicated by a high level of creatinine in the blood)

During Kryxana treatment, you may also have side effects of abnormal blood test results which can give your doctor information on the functioning of some parts of your body:

Frequent:

- Low levels of the following blood cells:
  - Lymphocyte, leukocytes, neutrophils, platelet count
- Low level of haemoglobin
- High levels of the following enzymes:
  - Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) (liver function)
- High level of creatinine

Advanced or metastatic breast cancer

The following side effects have been reported to be associated with Kryxana treatment of patients with advanced or metastatic breast cancer.

Some side effects could be serious

Tell your doctor immediately if you get any of the following symptoms during treatment with Kryxana:

- Fever, chills, weakness and frequent infections with symptoms such as sore throat or mouth ulcers (signs of a low level of different types of blood cells).
- Tiredness, itchy yellow skin or yellowing of the whites of your eyes, nausea or vomiting, loss of appetite, pain in the upper right side of the belly (abdomen), dark or brown urine, bleeding or bruising more easily than normal (these may be signs of a liver problem).
- Chest pain or discomfort, changes in heartbeat (fast or slow), palpitations, light headedness, fainting, dizziness, lips turning blue colour, shortness of breath, swelling (oedema) of your lower limbs or skin (these may be signs of heart problems).

- Serious infection with increased heart rate, shortness of breath or rapid breathing, fever and chills (these may be signs of sepsis which is an infection in the blood system which may be life threatening).
- Severe skin reaction that might include a combination of any of the following symptoms: rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms, enlarged lymph nodes (toxic epidermal necrolysis [TEN]).
- Inflammation of the lungs, which can cause shortness of breath and difficulty breathing. If severe, this can be life threatening (interstitial lung disease (ILD)/pneumonitis).

Your doctor may ask you to take a lower dose, interrupt your treatment with Kryxana, or stop it permanently.

Other possible side effects

Other side effects include the following listed below. If these side effects become severe, tell your doctor, pharmacist or nurse.

Frequent

- Tiredness, pale skin (potential sign of a low level of red blood cells, anaemia)
- Sore throat, runny nose, fever (signs of a respiratory tract infection)
- Painful and frequent urination (signs of a urinary tract infection)
- Reduced appetite
- Shortness of breath, difficulty breathing
- Back pain
- Nausea (feeling sick)
- Diarrhoea
- Vomiting

- Constipation
- Mouth sores with gum inflammation (stomatitis)
- Abdominal (belly) pain
- Upset stomach, indigestion, heartburn (dyspepsia)
- Hair loss or hair thinning (alopecia)
- Rash
- Itching (pruritus)
- Tiredness (fatigue)
- Weakness (asthenia)
- Fever (pyrexia)
- Headache
- Swollen hands, ankles or feet (peripheral oedema)
- Dizziness or light headedness
- Cough
- Liver damage (hepatotoxicity)

Less frequent

- Abdominal pain, nausea, vomiting and diarrhoea (signs of gastroenteritis, which is an infection of the gastrointestinal tract)
- Spontaneous bleeding or bruising (signs of a low level of blood platelets)
- Watering eyes

- Dry eyes
- Reduced level of calcium in the blood, which may sometimes lead to cramps
- Reduced level of phosphate in the blood
- Strange taste in the mouth (dysgeusias)
- Abnormal kidney blood test result (high level of creatinine in the blood)
- Skin reddening (erythema)
- Spinning sensation (vertigo)
- Dry skin
- Loss of skin colour in patches (vitiligo)
- Dry mouth
- Sore throat (oropharyngeal pain)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to patientsafety.sacg@novartis.com and via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Kryxana

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 the blister. The expiry date refers to the last day of that month.

Store at or below 25 °C.

Store in the original package in order to protect from moisture.

Do not take 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 Kryxana contains

- The active substance is ribociclib. Each film-coated tablet contains ribociclib succinate equivalent to 200 mg ribociclib.
- The other ingredients are:

  Tablet core: microcrystalline cellulose; crospovidone type A; low-substituted hydroxypropylcellulose; magnesium stearate; colloidal anhydrous silica.
  Coating material: iron oxide black (E172); iron oxide red (E172); soya lecithin (E322); polyvinyl alcohol (partially hydrolysed); talc; titanium dioxide (E171); xanthan gum.

What Kryxana looks like and contents of the pack

Kryxana is supplied as film-coated tablets in blisters.

The film-coated tablets are light greyish violet in colour, unscored, round, debossed with “RIC” on one side and “NVR” on the other side.

The following pack sizes are available: Packs containing 21, 42 or 63 film-coated tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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