

KRYXANA[®] Film-Coated Tablets

Consumer Medication Information Leaflet (RiMUP)

Ribociclib (200 mg)

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What Kryxana is used for

KRYXANA is a prescription medicine used to treat adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer:

- in combination with an aromatase inhibitor for stage II and III early breast cancer with a high risk of coming back.
- that has gotten worse or has spread to other parts of the body (advanced or metastatic breast cancer), in combination with:
 - an aromatase inhibitor as the first endocrine-based therapy in pre/perimenopausal or postmenopausal women or in men; or
 - fulvestrant as the first endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men.

It is not known if KRYXANA is safe and effective in children.

How Kryxana works

KRYXANA works by blocking the effects of enzymes called cyclin dependent kinases (CDK) which signal cancer cells to grow and divide to make new cells. By blocking these enzymes, KRYXANA can reduce cancer cell growth, the ability to make new cancer cells, and can kill cancer cells.

Before you use Kryxana

When you must not use it

- Avoid eating grapefruit and avoid grapefruit juice during treatment with KRYXANA since these may

increase the amount of KRYXANA in your blood.

- Do not breast-feed during your treatment with KRYXANA and for at least 3 weeks after the last dose of KRYXANA.

Before you start use it

Before you take KRYXANA, tell your healthcare provider about all of your medical conditions, including if you:

- have any heart problems, including heart failure, irregular heartbeats, and QT prolongation
- have ever had a heart attack
- have a slow heartbeat (bradycardia)
- have high blood pressure that is not controlled
- have decreased thyroid gland function (hypothyroidism)
- have problems with the amount of potassium, calcium, phosphorus, or magnesium in your blood
- have fever, chills, or any other signs or symptoms of infection
- have liver problems
- have kidney problems
- are pregnant, or plan to become pregnant. KRYXANA can harm your unborn baby.
 - if you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with KRYXANA.
 - females who are able to become pregnant and who take KRYXANA should use effective birth control during treatment and for at least 3 weeks after the last dose of KRYXANA.
 - talk to your healthcare provider about birth control methods that may be right for you during this time.
 - if you become pregnant or think you are pregnant, tell your healthcare provider right away.
- are breastfeeding or plan to breastfeed. It is not known if KRYXANA passes into your breast milk. Do not breastfeed during treatment with KRYXANA and for

at least 3 weeks after the last dose of KRYXANA.

Taking other medicines

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. KRYXANA and other medicines may affect each other causing side effects. Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How to use Kryxana

How much to use

Take KRYXANA exactly as your healthcare provider tells you. Do not change your dose or stop taking KRYXANA without talking to your healthcare provider. Take KRYXANA with or without food. Swallow KRYXANA tablets whole. Do not chew, crush, or split KRYXANA tablets before swallowing them. Do not take any KRYXANA tablets that are broken, cracked, or that look damaged.

When to use it

Take KRYXANA each day at about the same time, preferably in the morning.

How long to use it

Continue taking KRYXANA for as long as your doctor recommends.

If you forget to use it

If you miss a dose of KRYXANA or vomit after taking a dose of KRYXANA, do not take another dose on that day. Take your next dose at your regular time.

If you use too much (overdose)

If you take too much KRYXANA, call your healthcare provider right away or go to the nearest hospital emergency room.

While you are using Kryxana

Things you must do

Take your medicine exactly as your doctor has told you.

Things you must not do

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give KRYXANA to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of
Refer Side Effect Section

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

KRYXANA may cause serious side effects, including:

- **Lung problems.** KRYXANA may cause severe or life-threatening inflammation of the lungs during treatment that may lead to death. Tell your healthcare provider right away if you have any new or worsening symptoms, including:
 - trouble breathing or shortness of breath
 - cough with or without mucus
 - chest pain
- **Severe skin reactions.** Tell your healthcare provider or get medical help right away if you get severe rash or rash that keeps getting worse, reddened skin, flu-like symptoms, skin pain/burning, blistering of the lips, eyes or mouth, blisters on the skin or skin peeling, with or without fever.
- **Heart rhythm problems (QT prolongation).** KRYXANA can cause a heart problem known as QT prolongation. This condition can cause an abnormal heartbeat and may lead to death. Your healthcare provider should check your heart and do blood tests before and during treatment with KRYXANA. Tell your healthcare provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you feel dizzy or faint.
- **Liver problems.** KRYXANA can cause serious liver problems. Your healthcare provider should do blood

tests to check your liver before and during treatment with KRYXANA. Tell your healthcare provider right away if you get any of the following signs and symptoms of liver problems:

- yellowing of your skin or the whites of your eyes (jaundice)
- dark or brown (tea-colored) urine
- feeling very tired
- loss of appetite
- pain on the upper right side of your stomach area (abdomen)
- bleeding or bruising more easily than normal

- **Low white blood cell counts (neutropenia).** Low white blood cell counts are very common during treatment with KRYXANA and may result in infections that may be severe. Your healthcare provider should check your white blood cell counts before and during treatment with KRYXANA. Tell your healthcare provider right away if you have signs and symptoms of low white blood cell counts or infections such as fever and chills.
- Your healthcare provider may tell you to decrease your dose, temporarily stop or completely stop taking KRYXANA if you develop certain serious side effects during treatment with KRYXANA.

The most common side effects of KRYXANA in people with early breast cancer include:

- decreased white blood cell counts
- decreased red blood cell counts
- increased liver function tests
- infections
- nausea
- increased kidney function test
- tiredness
- decreased platelet counts
- headache

KRYXANA in people with advanced or metastatic breast cancer include:

- decreased white blood cell counts
- decreased red blood cell counts
- increased liver function tests
- infections
- nausea
- increased kidney function test
- tiredness
- decreased platelet counts

- diarrhea
- vomiting
- headache
- constipation
- hair loss
- cough
- rash
- back pain
- low blood sugar level

KRYXANA may cause fertility problems in males, which may affect your ability to father a child. Talk to your healthcare provider if this is a problem for you.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of KRYXANA. For more information, ask your healthcare provider or pharmacist.

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 Kryxana

Storage

Do not store KRYXANA above 30°C. Store in the original package in order to protect from moisture. Keep of the reach and sight of children.

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

- KRYXANA is supplied as film coated tablets in aluminum blisters.
- The film coated tablets are light greyish violet, round, curved with beveled edges, debossed with “RIC” on one side and “NVR” on the other side.

Ingredients

Active ingredient:

Ribociclib

Inactive ingredients:

colloidal silicon dioxide, crospovidone, hydroxypropylcellulose, magnesium stearate and microcrystalline cellulose. The film-coating contains iron oxide black, iron oxide red, lecithin (soya), polyvinyl alcohol (partially hydrolyzed), talc, titanium dioxide, and xanthan gum.

MAL number:

MAL18046001ARZ

Manufacturer

Novartis Pharmaceutical Manufacturing
LLC, Verovskova ulica 57, 1000
Ljubljana, Slovenia

Product Registration Holder

Novartis Corporation (Malaysia) Sdn.
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