Patient Information Leaflet

SCHEDULING STATUS

S4

Xeloda® 150, film-coated tablet

Xeloda® 500, film-coated tablet

Capecitabine

Contains sugar (anhydrous lactose)

Read all of this leaflet carefully before you start using Xeloda

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Xeloda 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.
- If any of the side effects gets serious, or if notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

1. What Xeloda is and what it is used for

Xeloda belongs to the group of medicines called "cytostatic agents", which stop the growth of cancer cells.

Xeloda contains capecitabine, which itself is not a cytostatic agent. Only after being absorbed by the body (more in tumour tissue than in normal tissue) is it changed into an active anti-cancer agent.

Xeloda is indicated for the treatment of colon, rectal, gastric, or breast cancers and may be used either alone or in combination with other anti-cancer medicines.

2. What you need to know before you take Xeloda

Do not take Xeloda:

- if you are allergic (hypersensitive) to capecitabine or any of the other ingredients of Xeloda. You must inform your doctor if you know that you have an allergy or over-reaction to Xeloda
- if you previously have had severe reactions to fluoropyrimidine therapy (a group of anticancer medicines such as fluorouracil)
- if you are pregnant or breastfeeding your baby
- if you have blood disorders, e.g. severely low levels of white cells or platelets in the blood (leucopenia, neutropenia or thrombocytopenia)
- if you have severe liver or kidney problems
- if you have a known deficiency for the enzyme dihydropyrimidine dehydrogenase (DPD), or
- if you are being treated now or have been treated in the last 4 weeks with brivudine, sorivudine or similar classes of substance as part of herpes zoster (chickenpox or shingles) therapy.

Warnings and precautions

Before treatment with Xeloda, make sure your doctor knows if you

- have liver or kidney diseases
- have or had other illnesses, such as heart problems or chest pain
- have brain diseases (for example, cancer that has spread to the brain, or nerve damage (neuropathy)
- have calcium imbalances
- have diabetes
- have diarrhoea

- are or become dehydrated
- have imbalances of ions in your blood (electrolyte imbalances, seen in tests)
- have a history of eye problems as you may need extra monitoring of your eyes
- have a severe skin reaction.

DPD deficiency: DPD deficiency is a rare condition present at birth that is not usually associated with health problems unless you receive certain medicines. If you have an unrecognised DPD deficiency and take Xeloda, you are at an increased risk of acute early-onset of severe forms of the side effects listed under section 4 Possible side effects. Contact your doctor immediately if you are concerned about any of the side effects or if you notice any additional side effects not listed in the leaflet (see section 4 Possible side effects).

Children and adolescents

Xeloda is not indicated in children and adolescents. Do not give Xeloda to children and adolescents.

Other medicines and Xeloda

Taking other medicines with Xeloda:

Before starting treatment, please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including traditional or complementary medicines or medicines obtained without a prescription. This is extremely important, as taking more than one medicine at the same time can strengthen or weaken the effect of the other medicines. You need to be particularly careful if you are taking any of the following while taking Xeloda:

- gout medicines (e.g. allopurinol)
- blood-thinning medicines (e.g. warfarin)
- certain anti-viral medicines (e.g. sorivudine and brivudine) or
- medicines for seizures (e.g. phenytoin).

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Taking Xeloda with food and drink

Take the tablets within 30 minutes after the end of a meal (breakfast and dinner) and swallow whole with water**. Do not crush or cut tablets**. If you cannot swallow Xeloda tablets whole, tell your healthcare provider.

Pregnancy, breastfeeding and fertility

Before starting treatment, you must tell your doctor if you are pregnant, if you think you are pregnant or if you intend to become pregnant. You should not take Xeloda if you are pregnant or think you might be. You should not breastfeed if you are taking Xeloda and for 2 weeks after the last dose. Ask your doctor or pharmacist for advice before taking any medicine.

If you are a woman who could become pregnant you should use effective contraception during treatment with Xeloda and for 6 months after the last dose.

If you are a male patient and your female partner could become pregnant, you should use effective contraception during treatment with Xeloda and for 3 months after the last dose.

Driving and using machines

Xeloda may make you feel dizzy, nauseous or tired. It is therefore possible that Xeloda could affect your ability to drive a car or operate machinery.

Xeloda contains

Xeloda contains anhydrous lactose (a sugar) as an excipient. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Xeloda.

3. How to take Xeloda

Xeloda tablets should be swallowed with water. Your doctor will prescribe a dose and treatment regimen that is right for you. Xeloda tablets are usually taken for 14 days followed by a 7 day rest period (when no tablets are taken). This 21 day period = one treatment cycle.

In combination with other medicines you may need to take the tablets over a different time period (e.g. every day, with no rest period). Your doctor will tell you what dose you need to take, when to take it and for how long you need to take it.

Your doctor may want you to take a combination of tablets.

- Take these tablets in the combination prescribed by your doctor
- Take the tablets within **30 minutes after the end of a meal** (breakfast and dinner)
- It is important that you take all your medication as prescribed by your doctor.

If you take more Xeloda than you should:

Contact your doctor or pharmacist before taking the next dose.

If you forget to take Xeloda:

Do **not** take the missed dose at all and do **not** double the next one. Instead, continue your regular dosing schedule and check with your doctor.

If you stop taking Xeloda:

There are no side effects caused by stopping treatment with Xeloda. In case you are using warfarin, stopping Xeloda might require that your doctor adjusts your warfarin dose. If you have any further questions on the use of Xeloda, ask your doctor or pharmacist.

4. Possible side effects

Xeloda can cause side effects. When used alone, the most common side effects which may affect more than 1 person in 10 are:

- diarrhoea, nausea, vomiting, stomatitis (sores in mouth and throat) and abdominal pain
- hand-and-foot skin-reaction (palms of the hands or soles of the feet tingle, become numb, painful, swollen or red), rash, dry or itchy skin
- tiredness

- loss of appetite (anorexia).

These side effects can become severe; therefore, it is important that you **always contact your doctor immediately** when you start to experience a side effect. Your doctor may instruct you to decrease the dose and/or temporarily discontinue treatment with Xeloda. This will help reduce the likelihood that the side effect continues or becomes severe.

STOP taking Xeloda immediately and contact your doctor if any of these symptoms occur:

- ***Diarrhoea***: if you have an increase of 4 or more bowel movements compared to your normal bowel movements each day or any diarrhoea at night.
- ***Vomiting***: if you vomit more than once in a 24-hour time period.
- ***Nausea:*** if you lose your appetite, and the amount of food you eat each day is much less than usual.
- ***Stomatitis***: if you have pain, redness, swelling or sores in your mouth.
- ***Hand-and-foot skin-reaction:*** if you have pain, swelling, and redness of hands and/or feet
- ***Fever or Infection:*** if you have a temperature of 38 °C or greater, or other signs of infection.
- ***Chest pain:*** if you experience pain localised to the centre of the chest, especially if it occurs during exercise.
- ***Steven-Johnson syndrome:*** if you experience painful red or purplish rash that spreads and blisters and/or other lesions begin to appear in the mucous membrane (e.g. mouth and lips), in particular if you had before light sensitivity, infections of the respiratory system (e.g. bronchitis) and/or fever.

If caught early, these side effects usually improve within 2 to 3 days after treatment discontinuation. If these side effects continue, however, contact your doctor immediately. Your doctor may instruct you to restart treatment at a lower dose.

Frequent side effects

- decreases in the number of white blood cells or red blood cells
- dehydration, weight loss

- headache, sleepiness, dizziness, abnormal sensation in the skin (numbness or tingling sensation), taste changes
- sleeplessness, (insomnia), depression
- eye irritation, increased tears, eye redness (conjunctivitis)
- inflammation of the veins (thrombophlebitis)
- shortness of breath, nose bleeds, cough, runny nose
- cold sores or other herpes infections
- infections of the lungs or respiratory system (e.g. pneumonia or bronchitis)
- bleeding from the gut, constipation, heartburn, pain in upper abdomen, indigestion, excess wind, dry mouth
- skin rash, hair loss (alopecia), skin reddening, dry skin, itching (pruritus), skin discolouration, skin loss, skin inflammation, nail disorder
- pain in the joints, or in the limbs (extremities), chest or back
- fever, swelling in the limbs, feeling ill
- problems with liver function (seen in blood tests) and increased blood bilirubin (excreted by the liver)

Less frequent side effects

- weariness
- weakness
- loss of weight
- irregular heartbeat and palpitations (arrhythmias), chest pain and heart attack (infarction)
- kidney failure
- liver failure
- difficulty speaking, impaired memory, loss of movement coordination, balance disorder, fainting, nerve damage (neuropathy) and problems with sensation
- blood infection, urinary tract infection, infection of the skin, infections in the nose and throat
- increased blood triglycerides

- skin ulcer and blister, reaction of the skin with sunlight, reddening of palms, swelling or pain of the face
- joint swelling or stiffness, bone pain, muscle weakness or stiffness
- specific changes in the electrocardiogram (QT prolongation)
- certain types of arrhythmia (including ventricular fibrillation, torsade de pointes, and bradycardia)
- eye inflammation causing eye pain and possibly eyesight problems
- inflammation of the skin causing red scaly patches due to an immune system illness
- severe skin reaction such as skin rash, ulceration and blistering which may involve ulcers of the mouth, nose, genitalia, hands, feet and eyes (red and swollen eyes)

If you are concerned about these or any other unexpected effect(s), talk to your doctor. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA 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 Xeloda.

5. How to store Xeloda

Store out of the reach and sight of children.

Xeloda 150 should be stored at or below 30 ^{o}C. Store in the original package in order to protect from moisture.

Xeloda 500 should be stored at or below 30 ^{o}C. Store in the original package in order to protect from moisture.

Do not use Xeloda after the expiry date on the outer pack and label.

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.

6. Contents of the pack and other information

What Xeloda contains

Xeloda 150: Each tablet contains 150 mg capecitabine

Xeloda 500: Each tablet contains 500 mg capecitabine

Other ingredients are: anhydrous lactose, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, talc, titanium dioxide (E171), yellow and red iron oxide (E172).

What Xeloda looks like and contents of the pack

Xeloda 150: A light peach biconvex film-coated oblong-shaped tablet with **Xeloda** engraved on one face and **150** engraved on the reverse. 60 film-coated tablets in a plastic bottle or blister pack.

Xeloda 500: A peach biconvex film-coated oblong-shaped tablet with **Xeloda** engraved on one face and **500** engraved on the reverse. 120 film-coated tablets in a plastic bottle or blister pack.

Holder of Certificate of Registration

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