

## PATIENT INFORMATION LEAFLET

### Read all of this leaflet carefully before you start taking Xeloda

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

### SCHEDULING STATUS

S4

### PROPRIETARY NAME AND DOSAGE FORM

**Xeloda® 150** film-coated tablet

**Xeloda® 500** film-coated tablet

### WHAT Xeloda CONTAINS

Xeloda 150: Each tablet contains 150 mg capecitabine

Xeloda 500: Each tablet contains 500 mg capecitabine

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

### WHAT Xeloda 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.

### 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 are pregnant or nursing,

- if you have blood disorders,
- if you have liver ailments 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.

**Take special care with Xeloda:** 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
- have calcium imbalances
- have diabetes

**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).

**Taking Xeloda with food and drink:** Take Xeloda no later than 30 minutes after meals.

**Pregnancy and breastfeeding:** 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. Ask your doctor or pharmacist for advice before taking any medicine.

**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.

### **Important information about some of the ingredients of Xeloda:**

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.

### **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 agents 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 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.

### **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.

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.

Other less common side effects which may affect between 1 and 10 people in 100 have been seen: decreases in the number of white blood cells or red blood cells, skin rashes, hair loss, weariness, fever, weakness, drowsiness, headache, numbness or tingling sensations, taste changes, dizziness, sleeplessness, swelling in the legs, constipation, dehydration, cold sores, inflammation of the nose and throat, chest infection, depression, problems with the eyes, inflammation of the veins (thrombophlebitis), shortness of breath, nose bleeds, cough, runny nose, bleeding from the gut, heartburn, excess wind, dry mouth, skin discolouration, nail disorder, pain in the joints, chest or back and loss of weight.

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.

### **STORING AND DISPOSING OF Xeloda**

Keep out of the reach and sight of children

Xeloda 150 should be stored at or below 25 °C.

Xeloda 500 should be stored at or below 30 °C.

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.

## **PRESENTATION**

Xeloda 150: 60 film-coated tablets in a plastic bottle or blister pack.

Xeloda 500: 120 film-coated tablets in a plastic bottle or blister pack.

## **IDENTIFICATION**

Xeloda 150: A light peach biconvex film-coated oblong-shaped tablet with **Xeloda** engraved on one face and **150** engraved on the reverse.

Xeloda 500: A peach biconvex film-coated oblong-shaped tablet with **Xeloda** engraved on one face and **500** engraved on the reverse

## **REGISTRATION NUMBERS**

Xeloda 150: 33/26/0198

Xeloda 500: 33/26/0199

## **NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION**

Roche Products (Pty) Ltd

24 Fricker Road

Illovo, Gauteng

South Africa

Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

## **DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET**

Date of registration: 24 August 2000

Last revision: 25 November 2011