

XELODA(R) Film-Coated Tablets

pronounced zeh-LOE-duh

contains the active ingredient capecitabine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about XELODA tablets. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking XELODA tablets against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What XELODA is used for

XELODA contains the active ingredient capecitabine.

XELODA is used for the treatment of breast cancer. It may be prescribed alone or in combination with a chemotherapy agent.

XELODA is also used for the treatment of colorectal cancer.

XELODA belongs to a group of medicines called anti-neoplastic agents. Within this group, XELODA belongs to a class of medicines called pyrimidine analogues.

XELODA works by killing or stopping the growth of cancer cells.

The medicine contained in XELODA tablets, capecitabine, is converted by the liver and cancer cells to another medicine called fluorouracil, also known as 5-FU.

It is 5-FU that acts to kill or stop the growth of cancer cells.

Your doctor may have prescribed XELODA for another purpose.

Ask your doctor if you have any questions why XELODA has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take XELODA

When you must not take it

Do not take XELODA if:

- 1. you have had an allergic reaction to XELODA or any ingredients listed at the end of this leaflet**
- 2. if you have allergies to 5-FU (another medicine used to treat cancer)**
- 3. if you have severe renal impairment**
- 4. if you have known dihydropyrimidine dehydrogenase (DPD) deficiency**

5. the package is torn or shows signs of tampering

6. the expiry date (EXP) printed on the pack has passed

If you take this medicine after the expiry date has passed, it may not work as well.

7. you are pregnant or plan to become pregnant

XELODA may be harmful to an unborn baby when taken by a pregnant woman. It is recommended that you not take XELODA while you are pregnant.

If you are not sure if you should be taking XELODA, talk to your doctor.

Use in children

Do not give XELODA to children.

Safety and effectiveness in persons less than 18 years of age have not been established.

Use in elderly

The same dose is recommended for elderly patients given XELODA alone. A lesser dose may be required for elderly patients given XELODA in combination with a chemotherapy agent. Please follow your doctor's instructions carefully.

Before you start to take it

Your doctor must know about all the following before you start to take XELODA.

Tell your doctor if:

1. you are pregnant or plan to become pregnant

XELODA may be harmful to an unborn baby when taken by a pregnant woman. It is not recommended that you take XELODA while you are pregnant.

2. you are breast-feeding or plan to breast-feed

It is not known whether capecitabine and 5-FU pass into breast milk. In any case, it is not recommended that you breast-feed while taking XELODA.

3. you have any other health problems, especially the following:

- * heart disease
- * liver disease
- * kidney disease

4. you are allergic to any other medicines, foods, dyes or preservatives

If you have not told your doctor about any of the above, tell them before you start taking XELODA.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or healthfood shop.

Some medicines may interfere with XELODA. These medicines include:

- * sorivudine (antiviral agent), a medicine used to treat varicella zoster virus (shingles) and herpes simplex virus (cold sore).

There are some medicines that may still be taken with XELODA but may require close supervision by your doctor. These medicines include:

- * warfarin (Coumadin(R)),

Marevan(R)), a medicine used to thin the blood

- * phenytoin (Dilantin(R)), a medicine used to treat epilepsy
- * antacids, medicines used to treat heartburn or indigestion

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking XELODA.

How to take XELODA

How much to take

Take XELODA exactly as your doctor has prescribed.

Your doctor will tell you how many XELODA tablets to take each day.

Your doctor will calculate the dose based on your height and weight.

Your doctor may want you to take a combination of 150 mg (light peach) and 500 mg (peach) tablets for each dose.

If a combination of tablets is prescribed, it is very important that you correctly identify the tablets.

Your doctor may vary your dose depending on the nature of your illness and your response to XELODA. Elderly patients may need to receive less.

How to take it

Swallow tablets whole with a glass of water.

Do not chew the tablets.

When to take it

Take XELODA tablets in the morning and evening (ideally every 12 hours) within 30 minutes after the end of a meal (breakfast and dinner).

How long to take XELODA

The duration of treatment with XELODA varies, depending on the nature of your illness and your individual response to the treatment.

It is usually recommended that XELODA be taken for 14 days followed by a 7 day rest period (no medicine) given as a 21 day cycle. Your doctor will determine how many cycles of treatment you will need.

Continue taking XELODA until your doctor tells you to stop.

If you forget to take XELODA

Do not take an extra dose. Wait until the next dose and take your normal dose then.

Do not try to make up for the dose that you missed by taking more than one dose at a time.

If you are not sure what to do, ask your doctor or pharmacist.

In case of an overdose

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much XELODA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking XELODA

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking XELODA.

Tell your doctor if you become pregnant while taking XELODA.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you know of any renal impairment that you may have.

Your doctor may either prescribe a different medicine or reduce the XELODA dose.

Tell your doctor if you feel the tablets are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Things you must not do

Do not stop taking XELODA or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give XELODA to anyone else even if they have the same condition as you.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how XELODA affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking XELODA.

XELODA helps people with colorectal cancer or breast cancer but it may have unwanted side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- * diarrhoea
 - If you have more than 4 bowel movements each day or any diarrhoea at night, you should stop taking XELODA and seek the advice of your doctor.
 - Your doctor may recommend that you take medication to help with the diarrhoea.
- * nausea (feeling as if you are about to vomit)
 - If you feel XELODA has reduced your appetite significantly because of nausea, stop taking XELODA and seek the advice of your doctor.
 - Your doctor may prescribe medication to help with your nausea.
- * vomiting
 - If you vomit more than once in a 24 hour period, stop taking XELODA and seek the advice of your doctor.
 - Your doctor may prescribe medication to help with the vomiting.
- * hand- foot syndrome
 - If you experience pain, redness or swelling of the hands and/or feet that affects your normal activities, stop taking XELODA and seek the advice of your doctor.
- * stomatitis (pain, redness, swelling or sores in the mouth)
 - If you experience pain, redness, swelling or ulcers in the mouth, but are still able to eat, you should stop taking XELODA and seek the advice

of your doctor.

- * fatigue (tiredness), weakness or weariness
- * skin rashes, dry or itchy skin
- * abdominal (gut) pain
- * fever
- * constipation
- * headache
- * dizziness
- * loss of appetite

These are the more common side effects of XELODA that you are likely to notice. Your doctor will tell you more about them. Your doctor may also recommend that you change the dose of XELODA that you are taking if you experience any of the above side effects.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

These side effects may differ when taking XELODA in combination with a chemotherapy agent.

Please consult your doctor for possible side effects that may be caused by taking XELODA with a chemotherapy agent.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking XELODA

Storage

Keep your tablets in their container until it is time to take them.

If you take the tablets out of their container they may not keep well.

Keep XELODA in a cool dry place where the temperature stays below 30 degrees C.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep XELODA where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking XELODA, or the medication has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

Availability

XELODA is available in two strengths, 150 mg and 500 mg.

XELODA comes in blister packs in the following pack sizes:

- * 150 mg - 60 tablets
- * 500 mg - 120 tablets

What XELODA looks like

- * XELODA 150 mg tablets are light peach coloured and oblong-shaped. They are engraved with "XELODA" on one face and "150" on the other.
- * XELODA 500 mg tablets are peach coloured and oblong-shaped. They are engraved with "XELODA" on one face and "500" on the other.

Ingredients

Active ingredient

- * capecitabine

Inactive ingredients

- * lactose
- * croscarmellose sodium
- * hypromellose
- * microcrystalline cellulose
- * magnesium stearate

The tablets have a film-coating which contains:

- * hypromellose
- * talc
- * titanium dioxide
- * iron oxide yellow (CI77492)
- * iron oxide red (CI77491)

XELODA tablets are gluten free.

Distributor

XELODA is distributed by:

Roche Products Pty Limited

ABN 70 000 132 865

4-10 Inman Road

Dee Why NSW 2099

Customer enquiries: 1 800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information

Australian Registration Numbers

- * 150 mg: AUST R 75731
- * 500 mg: AUST R 75732

This leaflet was prepared on 22 November 2005.