

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

XELODA is used to treat cancer of the bowel and rectum (colorectal), oesophagus, stomach and breast. It may be prescribed alone or in combination with other medicines used to treat cancer.

Cancer is a disease of the cells, which are the body's building blocks. Our bodies constantly make new cells.

Our genes control the way the body's cells grow and behave. Cancers are caused by damage to these genes. Damaged genes causes cells to grow abnormally.

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 5-fluorouracil (also called 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.

XELODA is not addictive.

Before you take XELODA

When you must not take it

Do not take XELODA if:

- 1. you have had an allergy to**
 - * **capecitabine or any of the ingredients listed at the end of this leaflet**

- * **5-fluorouracil (also called 5-FU), a medicine used to treat cancer**
- * **Other fluoropyrimidine medicines**

Some of the symptoms of an allergic reaction may include:

- * shortness of breath
- * wheezing or difficulty in breathing
- * swelling of the face, lips, tongue or other parts of the body
- * rash, itching, hives on the skin

2. if you have severe kidney disease

3. if you have known dihydropyrimidine dehydrogenase (DPD) deficiency

4. you are taking a medicine containing sorivudine or brivudine

Taking sorivudine or brivudine at the same time as XELODA is potentially fatal.

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.

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.

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. Additionally, if you are a woman, you should use effective contraception to avoid becoming pregnant while you are taking XELODA.

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

It is not known whether XELODA and 5-FU pass into breast milk. You doctor will discuss the risks and benefits of you taking XELODA if you are breast-feeding.

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

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

4. you are dehydrated

some signs and symptoms of dehydration include:

- * dry skin
- * dark coloured urine
- * thirst
- * weakness or fatigue
- * loss of appetite

5. 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 without a prescription from a pharmacy, supermarket or healthfood shop.

Some medicines may interfere with XELODA. These medicines include:

- * warfarin (Coumadin(R), Marevan(R)), a medicine used to thin the blood
- * phenytoin (Dilantin(R)), a medicine used to treat epilepsy and heart irregularities
- * leucovorin, also called folinic acid, a medicine used to treat folic acid deficient anaemias
- * antacids, medicines used to treat heart burn or indigestion

These medicines may be affected by XELODA, or may affect how well XELODA works. You may need to use different amounts of your medicines, or take different medicines. Your doctor will advise you.

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 and how often to take them.

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 colour) and 500 mg (peach colour) 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.

Use in elderly

The same dose is recommended for elderly patients given XELODA alone. A lower dose may be given to elderly patients taking XELODA in combination with other medicines to treat cancer. Please follow your doctor's instructions carefully.

How to take it

Swallow the tablets whole with a glass of water.

Do not chew the tablets.

When to take it

Take XELODA tablets twice a day (morning and evening).

Take XELODA tablets during or within 30 minutes after a meal.

Take XELODA tablets at about the same time each day

Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

If you are not sure when to take XELODA, ask your doctor.

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.

Your XELODA therapy is made up of a series of treatment cycles which usually lasts for 21 days. Your doctor will advise you how many cycles of treatment you will have and whether there are any rest days in the cycle.

In most cases, your treatment cycle will consist of intermittent XELODA therapy, where you will take XELODA for 14 days, followed by a rest period of 7 days. During the rest period, you will not take any XELODA.

Alternatively, your treatment cycle may be continuous, which involves 21 days of XELODA treatment and no rest period.

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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia telephone 13 11 26; New Zealand telephone 0800 764 766) 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 immediately if you develop diarrhoea (more than 4 bowel movements each day).

XELODA can sometimes cause diarrhoea in some people. Your doctor may stop your XELODA treatment and treat your diarrhoea before starting you on XELODA tablets again.

Tell your doctor immediately if you develop nausea (feeling like you want to vomit) and it has affected your appetite significantly.

XELODA can cause nausea in some people. Your doctor may stop your XELODA treatment and treat your nausea before starting you on XELODA tablets again.

Tell your doctor immediately if you develop vomiting, and vomit more than once in a 24 hour period..

XELODA can cause vomiting in some people. Your doctor may stop your XELODA treatment and treat your vomiting before starting you on XELODA tablets again.

Tell your doctor immediately if you develop redness or swelling of your hands and/or feet that affects your normal activities

XELODA can cause redness and swelling of hands and/or feet that can affect your normal activities. Your doctor may decide to treat this with other medicines, and/or stop your XELODA treatment until the side effect settles.

Tell your doctor immediately if you develop pain, redness, swelling or sores in the mouth.

XELODA can cause pain, redness, swelling or sores in the mouth in some people. Your doctor may treat this with other medicines, and/or may decide to stop your XELODA treatment until the side effect settles.

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 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 bowel cancer, breast cancer, stomach cancer and cancer of the oesophagus, 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
- * vomiting
- * nausea (feeling like you want to vomit)
- * fatigue (tiredness), weakness or weariness
- * skin rashes, dry or itchy skin
- * abdominal (gut) pain
- * fever
- * constipation
- * headache
- * dizziness
- * loss of appetite, weight loss
- * hair loss
- * increased eye watering or irritation
- * taste disturbance
- * indigestion
- * dry mouth
- * nail disorders
- * sore throat, cough, nose bleeds
- * shortness of breath
- * muscle and joint pain

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.

Tell your doctor immediately and stop taking XELODA if you notice any of the following:

- * severe diarrhoea with more than 4 bowel movements each day
- * nausea that has reduced your appetite significantly
- * vomiting more than once in a 24 hour period

- * pain, redness and/or swelling of your hands and/or feet that has affected your normal activities (hand-foot-syndrome)
- * pain, redness, swelling or ulcers in the mouth (stomatitis)

You need to stop taking XELODA if you experience the above side effects. Your doctor will treat your side effects before they start you on XELODA again.

Tell your doctor immediately or go to your nearest Accident and Emergency centre if you notice any of the following:

- * chest pain
- * irregular heart beat
- * confusion
- * poor balance or lack of co-ordination
- * signs of infection such as swelling, redness and increased temperature
- * signs of liver disease such as yellowing of the skin and eyes
- * blood in the faeces

These are serious side effects. You may need urgent medical attention.

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 medicine.

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

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on 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 side and "150" on the other.
- * XELODA 500 mg tablets are peach coloured and oblong-shaped. They are engraved with "XELODA" on one side and "500" on the other.

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 08 July 2009

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 in Australia by:

Roche Products Pty Limited
ABN 70 000 132 865
4-10 Inman Road
Dee Why NSW 2099
Customer enquiries: 1 800 233 950

Distributed in New Zealand by:
Roche Products (New Zealand) Limited
PO Box 12494, Penrose
Auckland 1642
NEW ZEALAND
Customer enquiries: 0800 656 464