

XELOKITABINE

Film-Coated Tablets

contains the active ingredient capecitabine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Xelocitabine 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 this medicine 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 this medicine is used for

Xelocitabine contains the active ingredient capecitabine. Xelocitabine belongs to a group of medicines called anti-neoplastic agents. Within this group, Xelocitabine belongs to a class of medicines called fluoropyrimidine analogues.

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

The medicine contained in Xelocitabine 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 Xelocitabine for another purpose.

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

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

Xelocitabine is not addictive.

Before you take this medicine

When you must not take it

Do not take Xelocitabine if:

- 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
- if you have severe kidney disease**
- if you have known dihydropyrimidine dehydrogenase (DPD) deficiency**
- you are taking a medicine containing sorivudine or brivudine**

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

- the package is torn or shows signs of tampering**
- 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 Xelocitabine, talk to your doctor.

Use in children

Do not give this medicine to children.

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

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- **any of the ingredients listed at the end of this leaflet**
- **any other medicines**
- **any other substances, such as foods, preservatives or dyes.**

Tell your doctor if:

- you are pregnant or plan to become pregnant**

Xelocitabine may be harmful to an unborn baby when taken by a pregnant woman. It is not recommended that you take Xelocitabine while you are pregnant. Additionally, if you are a woman, you should use effective contraception to avoid becoming pregnant while you are taking Xelocitabine.

- you are breast-feeding or plan to breast-feed**

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

- you have any other health problems, especially the following:**

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

- you are dehydrated**

- some signs and symptoms of dehydration include:
 - dry skin
 - dark coloured urine
 - thirst
 - weakness or fatigue
 - loss of appetite

- you plan to have surgery.**

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

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 health food shop.

Some medicines may interfere with Xelocitabine. These medicines include:

- warfarin (Coumadin®, Marevan®), a medicine used to thin the blood
- phenytoin (Dilantin®), a medicine used to treat epilepsy and heart irregularities

- leucovorin, also called folic 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 Xelocitabine, or may affect how well Xelocitabine 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 Xelocitabine.

How to take Xelocitabine

How much to take

Take Xelocitabine exactly as your doctor has prescribed.

Xelocitabine may be given with or without chemotherapy. Your doctor will tell you how many Xelocitabine 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 Xelocitabine. Elderly patients may need to receive less.

Use in elderly

The same dose is recommended for elderly patients given Xelocitabine alone. A lower dose may be given to elderly patients taking Xelocitabine 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 Xelocitabine tablets twice a day (morning and evening).

Xelocitabine tablets should be taken with food. You should take Xelocitabine no later than 30 minutes after food.

Take Xelocitabine 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.

When taken in combination with chemotherapy, your doctor will advise which days of your treatment cycle Xelocitabine should be taken.

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

How long to take it

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

Your Xelocitabine 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 Xelocitabine therapy, where you will take Xelocitabine for 14 days, followed by a rest period of 7 days. During the rest period, you will not take any Xelocitabine.

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

Continue taking Xelocitabine until your doctor tells you to stop.

If you forget to take Xelocitabine

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) 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 Xelocitabine.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Xelocitabine

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are using this medicine.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using this medicine.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are using this medicine.

If you become pregnant while taking Xelocitabine, stop using it and tell your doctor immediately.

Tell your doctor immediately if you develop diarrhoea (more than 4 bowel movements each day).

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

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

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

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

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

Tell your doctor immediately if you develop redness or swelling of your hands

and/or feet that affects your normal activities

Xelocitabine 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 capecitabine treatment until the side effect settles.

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

Xelocitabine 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 capecitabine 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 Xelocitabine 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 Xelocitabine to anyone else even if their symptoms seem similar to yours.

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 Xelocitabine affects you.

Side effects

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

Xelocitabine helps people with bowel cancer, breast cancer, stomach cancer and cancer of the oesophagus (food pipe), but it may have unwanted side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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, or increased temperature sensitivity

- constipation
- headache
- dizziness
- loss of appetite, weight loss
- hair loss
- increased eye watering or irritation, conjunctivitis (itchy eyes and crusty eyelids)
- taste disturbance
- indigestion, wind
- dry mouth, thirst
- sore mouth, mouth ulcers, cold sores
- nail disorders
- sore throat, cough, nose bleeds
- shortness of breath, difficulty in breathing, or tightening of the chest
- redness or swelling of your hands and/or feet
- tingling or numbness of the hands or feet
- muscle and joint pain
- dark coloured urine
- difficulty sleeping

These are the more common side effects of Xelocitabine 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 Xelocitabine that you are taking if you experience any of the above side effects.

Tell your doctor immediately and stop taking Xelocitabine 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 Xelocitabine if you experience the above side effects. Your doctor will treat your side effects before they start you on Xelocitabine again.

If any of the following happen, stop using this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- **swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing**
- **chest pain**
- **irregular heart beat**
- **shortness of breath**
- **confusion**
- **poor balance or lack of co-ordination**
- **numbness or weakness of arms or legs**
- **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 or hospitalisation.

These side effects are very rare.

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 Xelocitabine in combination with a chemotherapy medicine.

Please consult your doctor for possible side effects that may be caused by taking Xelocitabine 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 this medicine

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 Xelocitabine in a cool dry place where the temperature stays below 25°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 this medicine where 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 Xelocitabine, or the medication has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

Availability

Xelocitabine tablets are available in two strengths, 150 mg and 500 mg.

Xelocitabine tablets come in blister packs in the following pack sizes:

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

What Xelocitabine looks like

- 150 mg: Light peach film-coated tablet of biconvex, oblong shape with the marking "150" on one side and "RDY" on other side.
- 500 mg: Peach, film-coated tablet of biconvex, oblong shape with the marking "500" on one side and "RDY" on the other side.

Ingredients

Active ingredient

- capecitabine

Inactive ingredients

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

The tablets have a film-coating which contains:

- hypromellose
- purified talc

- titanium dioxide
- iron oxide yellow (CI77492)
- iron oxide red (CI77491)

Xelocitabine tablets are gluten free, tartrazine-free and free of other azo dyes.

Distributor:

Juno Pharmaceuticals Pty Ltd
Level 2, 6 Bond Street
South Yarra, VIC 3141

Australian Registration Number

Xelocitabine 150 mg Tablets: AUST R 282532

Xelocitabine 500 mg Tablets: AUST R 282531

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