

Xelabine

(Capecitabine film-coated Tablets 150 mg and 500 mg)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Xelabine 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 Xelabine 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 Xelabine is used for

Xelabine contains the active ingredient capecitabine.

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

Xelabine 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 Xelabine 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 Xelabine for another purpose.

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

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

Xelabine is not addictive.

Before you take Xelabine

When you must not take it

Do not take Xelabine 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 medicinesSome 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 Xelabine 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 Xelabine, talk to your doctor.

Use in children

Do not give Xelabine 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 Xelabine.

Tell your doctor if:

- 1. you are pregnant or plan to become pregnant**

Xelabine may be harmful to an unborn baby when taken by a pregnant woman. It is not recommended that you take Xelabine while you are pregnant. Additionally, if you are a woman, you should use effective contraception to avoid becoming pregnant while you are taking Xelabine.
- 2. you are breast-feeding or plan to breast-feed**

It is not known whether Xelabine and 5-FU pass into

breast milk. Your doctor will discuss the risks and benefits of you taking Xelabine if you are breast-feeding.

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

- heart disease
- liver disease
- kidney disease

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 Xelabine.

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 Xelabine. 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 Xelabine, or may affect how well Xelabine 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 Xelabine.

How to take Xelabine

How much to take

Take Xelabine exactly as your doctor has prescribed.

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

Use in elderly

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

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

Take Xelabine 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 Xelabine should be taken.

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

How long to take Xelabine

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

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

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

Continue taking Xelabine until your doctor tells you to stop.

If you forget to take Xelabine

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 Xelabine. 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 Xelabine

Things you must do

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

Tell your doctor if you become pregnant while taking Xelabine.

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

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

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

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

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

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

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

Xelabine 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 Xelabine treatment until the side effect settles.

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

Xelabine 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 Xelabine 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 Xelabine 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 Xelabine 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 Xelabine affects you.

Side effects

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

Xelabine 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. 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) 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)
- 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 Xelabine 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 Xelabine that you are taking if you experience any of the above side effects.

Tell your doctor immediately and stop taking Xelabine 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)
- passing little or no urine (this could be kidney disease) other symptoms include drowsiness, nausea, vomiting, breathlessness.

You need to stop taking Xelabine if you experience the above side effects. Your doctor will treat your side effects before they start you on Xelabine 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
- shortness of breath
- one or a combination of the following: confusion, disorientation or memory loss, changes in the way you move, walk or talk, decreased strength or progressive weakness in your body, blurred or loss of vision.
- poor balance or lack of coordination
- 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
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell.

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 Xelabine in combination with a chemotherapy medicine.

Please consult your doctor for possible side effects that may be caused by taking Xelabine 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 Xelabine

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 Xelabine 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 Xelabine 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 Xelabine, or the medication has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

Availability

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

Xelabine comes in blister packs in the following pack sizes:

- 150 mg – 30, 60, 120 tablets
- 500 mg - 30, 60, 120 tablets

What Xelabine looks like

Xelabine Tablets 150 mg are light peach coloured, oblong shaped, biconvex, film-coated tablets, debossed with “150” on one side and plain on other side.

Xelabine Tablets 500mg are peach coloured, oblong shaped, biconvex, film-coated tablets, debossed with “500” on one side and plain on other side.

Ingredients

Active ingredient:

Capecitabine

Inactive ingredients:

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

The tablets have a film-coating which contains:

- hypromellose
- purified talc
- titanium dioxide
- iron oxide yellow
- iron oxide red

Name and Address of the Sponsor

Aspen Pharma Pty Ltd
34-36 Chandos Street,
ST LEONARDS, NSW, 2065
Australia

Xelabine 150 mg:

AUST R 213042

Xelabine 500 mg:

AUST R 213045

Date of Preparation

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