

XELABINE

capecitabine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about XELABINE. 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 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.

This medicine is used to treat:

- cancer of the bowel and rectum (colorectal)
- breast cancer
- cancer of the stomach and food pipe (oesophagus)

This medicine belongs to a group of medicines called anti-neoplastic medicines. Within this group, XELABINE belongs to a class of medicines called fluoropyrimidine analogues.

The active ingredient, capecitabine, is converted in the body by the liver and cancer cells to a medicine called 5-fluorouracil (also called 5-FU). It is

5-FU that works to kill or stop the growth of cancer cells.

XELABINE may be prescribed alone or in combination with other medicines used to treat cancer, such as chemotherapy medicines.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

This medicine is not addictive. Before you take XELABINE

When you must not take it

Do not take XELABINE if you have an allergy to:

- any medicine containing capecitabine
- fluorouracil (also called 5-FU), a medicine used to treat cancer
- other fluoropyrimidine medicines
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

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

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy. Your

doctor may advise you to avoid becoming pregnant while taking this medicine.

Do not breast-feed if you are taking this medicine.

It is not known whether XELABINE and 5-FU pass into breast milk. Your doctor will discuss with you the risks and benefits involved.

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Do not take this medicine if you have or have had any of the following:

- severe kidney disease
- known dihydropyrimidine dehydrogenase (DPD) deficiency

Do not take this medicine if you are taking any medicines containing the following:

- sorivudine
- brivudine

These medicines are usually used to treat viral infections such as shingles, chicken pox, or cold sores (herpes simplex 1). Taking these medicines at the same time as XELABINE is potentially fatal.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart disease, coronary artery disease
- kidney disease
- liver disease

Tell your doctor if you are dehydrated. Some signs of dehydration include:

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

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 or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and XELABINE may interfere with each other. These include:

- warfarin, a medicine used to prevent blood clots and to thin the blood
- phenytoin, a medicine used to treat seizures, 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 it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take XELABINE

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Take XELABINE exactly as your doctor has told you to.

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 your dose based on your height and weight.

Your doctor may vary your dose depending on the nature of your illness and your response to XELABINE.

Use in elderly patients

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.

How to take it

Swallow the tablets whole with a full glass of water.

Do not chew the tablets.

When to take it

Take your medicine two times each day (morning and evening).

Taking it at the same times each day will have the best effect. It will also help you remember when to take it.

Take your medicine with food.

You should take XELABINE no later than 30 minutes after food.

When you take XELABINE in combination with chemotherapy, your doctor will advise which days of your treatment cycle you should take XELABINE.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

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

Your XELABINE therapy is made up of a series of treatment cycles which usually last 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 with no rest period.

If you forget to take it

Skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the 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. Some signs of an overdose may include, nausea, vomiting, diarrhoea or gastrointestinal irritation and bleeding.

While you are using XELABINE

Things you must do If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking XELABINE.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor immediately if you develop:

- diarrhoea (more than 4 bowel movements each day)
- nausea (feeling like you want to vomit) and it has affected your appetite significantly
- vomiting, and vomit more than once in a 24 hour period
- redness or swelling of your hands and/or feet that affects your normal activities, also called hand-foot syndrome
- pain, redness, swelling, sores or ulcers in the mouth

XELABINE can sometimes cause the above problems in some people. Your doctor may stop your treatment and treat these issues before starting you on XELABINE again.

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.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take XELABINE to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

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

Ensure that you remain well hydrated by drinking adequate amounts of water each day.

Side effects

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

This medicine helps most people with cancer, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

Tell your doctor or pharmacist 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, itchy or red skin
- pain in your abdomen (gut)
- fever, or increased temperature
- constipation
- headache
- dizziness
- loss of appetite, weight loss
- hair loss
- increased eye watering or irritation, conjunctivitis (itchy eyes and crusty eyelids)
- indigestion or wind (gas)
- dry mouth, thirst, dehydration, dark coloured urine
- 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
- altered sense of taste
- muscle and joint pain
- difficulty sleeping

The above list includes the more common side effects of your medicine. Your doctor may change your dose of XELABINE if you experience any of the above side effects.

Tell your doctor as soon as possible if you notice any of the following:

- severe diarrhoea with more than 4 bowel movements each day
- nausea that has significantly reduced your appetite
- 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 a sign of kidney disease)
- drowsiness
- breathlessness

You may need to stop taking XELABINE and be treated for the above side effects by your doctor, before starting XELABINE again.

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

- chest pain
- irregular heartbeat
- shortness of breath
- one or a combination of the following:
 - confusion
 - disorientation or memory loss
 - changes in the way you move, walk or talk
 - poor balance or lack of co-ordination
 - decreased strength or progressive weakness in your body
 - blurred or loss of vision
- numbness or weakness of arms and/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, or genitals
- severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin, accompanied by fever and chills, aching muscles and generally feeling unwell

The above list includes serious side effects. You may need urgent medical attention or hospitalisation.

These side effects may differ when taking XELABINE in combination with a chemotherapy medicine.

Ask your doctor for possible side effects that may be caused by taking XELABINE with a chemotherapy medicine

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using XELABINE

Storage

Keep your tablets in the pack until it is time to take them.

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

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store XELABINE or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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 this medicine or the expiry

date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

XELABINE tablets are peach coloured, oblong shaped, debossed with "500" on one side, and plain on the other side.

XELABINE tablets are available in blister packs of 120 tablets.

Ingredients

XELABINE contains 500 mg of capecitabine as the active ingredient.

The tablets also contain the following inactive ingredients:

- croscarmellose sodium
- hypromellose
- iron oxide red
- iron oxide yellow
- lactose
- magnesium stearate
- microcrystalline cellulose
- purified talc
- purified water
- titanium dioxide

XELABINE contains lactose.

Distributor

XELABINE is distributed in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

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