

Capecitabine APOTEX Tablets

Contains the active ingredient capecitabine

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Capecitabine APOTEX. It contains the active ingredient capecitabine.

It is used to treat cancer of the:

- bowel and rectum (colorectal)
- breast and stomach and food pipe (oesophagus).

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

Your doctor may have prescribed this medicine for another reason.

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

How it works

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

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.

There is no evidence that this medicine is addictive.

Use in children

Do not give capecitabine to children.

Safety and effectiveness of this medicine in persons under 18 years of age have not been established.

Before you use this medicine

When you must not use it

Do not use this medicine if:

- You have severe kidney disease.
- You have known dihydropyrimidine dehydrogenase (DPD) deficiency.
- You are taking a medicine containing sorivudine or related medicines such as brivudine. Taking these medicines at the same time as capecitabine is potentially fatal.
- You are hypersensitive to or have had an allergic reaction 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.Symptoms of an allergic reaction may include:
 - cough
 - shortness of breath
 - wheezing or difficulty in breathing
 - swelling of the face, lips, tongue, throat or other parts of the body
 - rash, itching or hives on the skin
 - fainting
 - hayfever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency Department at the nearest hospital. The expiry date (EXP) printed on the pack has passed.

- The packaging is torn, shows signs of tampering or it does not look quite right.

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

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - heart disease
 - liver disease
 - kidney disease.
3. You are pregnant or plan to become pregnant.

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

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

5. You are dehydrated.

Some signs and symptoms of dehydration include:
 - dry skin
 - dark coloured urine
 - thirst
 - weakness or fatigue
 - loss of appetite.
6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines, this includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

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

- medicines used to thin the blood such as warfarin and phenprocoumon
- phenytoin, 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 capecitabine or may affect the way it works. You may need different amounts of your medicines, or 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 this medicine

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

Their instructions may be different to the information in this leaflet.

If you are not sure how to take this medicine, ask your doctor or pharmacist for help.

How much to take

Take this medicine exactly as your doctor has prescribed.

Capecitabine may be given with or without chemotherapy.

Your doctor will tell you how much of this capecitabine you should take. This will depend on your condition, whether you are taking any other medicines and your height and weight. Elderly patients may be prescribed a lower dose.

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.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablets whole with a glass of water.

Do not chew the tablets.

When to take it

Capecitabine tablets should be taken with food. You should take this medicine no later than 30 minutes after food.

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

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

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

How long to take it

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

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

Make sure you have enough to last over weekends and holidays.

If you forget to take it

Skip the missed dose and take your next dose at the usual time.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

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 to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

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

You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breast-feeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Take this medicine exactly as your doctor has told you to.

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

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. Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.
- Let yourself run out of medicine over the weekend or on holidays.
- Give this medicine 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 capecitabine affects you.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking this medicine or if you have any questions or concerns.

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

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- diarrhoea
 - vomiting
 - nausea (feeling like you want to vomit)
 - fatigue (tiredness), weakness or weariness
 - skin rashes, discolouration, dry or itchy skin
 - abdominal (stomach) pain
 - fever, or increased temperature sensitivity
 - constipation
 - headache
 - dizziness
 - loss of appetite, weight loss
 - hair loss
 - increased eye watering or irritation, sensitivity to light, 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
 - back pain, muscle and joint pain
 - dark coloured urine
 - difficulty sleeping
 - infections
 - depression.
- Tell your doctor immediately 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 capecitabine if you experience the above side effects. Your doctor will treat your side effects before they start you on capecitabine again.

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

- chest pain
- irregular heart beat
- shortness of breath
- confusion
- 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.

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

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

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

Other side effects not listed above may occur in some patients.

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

Allergic reactions

If you think you are having an allergic reaction to capecitabine, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms.

Storage and disposal

Storage

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

If you take the tablets out of the blister pack it will not keep well.

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

Do not store your medicine, 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 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 this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What Capecitabine APOTEX looks like

- Capecitabine APOTEX 150 mg tablets: Light peach, oval, biconvex, film-coated tablet, engraved "APO" on one side, "C150" on the other side.
- Capecitabine APOTEX 500 mg tablets: Peach, oval, biconvex, film-coated tablet, engraved "APO" on one side, "C500" on the other side.

Ingredients

Capecitabine APOTEX tablets contain either 150 mg or 500 mg of capecitabine as the active ingredient.

They also contain the following inactive ingredients:

- anhydrous lactose
- croscarmellose sodium
- methylcellulose
- magnesium stearate
- silica - colloidal anhydrous
- hypromellose
- hydroxypropylcellulose
- macrogol 8000
- titanium dioxide
- iron oxide red CI77491
- iron oxide yellow CI77492.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Capecitabine APOTEX 150 mg tablets are available in:

- Blister packs of 60 tablets.
- Bottles of 1000 tablets.

Capecitabine APOTEX 500 mg tablets are available in:

- Blister packs of 120 tablets.
- Bottles of 500 tablets.

Not all strengths, pack types and/or pack sizes may be available.

Australian Registration Numbers

- Capecitabine APOTEX 150 mg tablet (blister pack):
AUST R 202726
- Capecitabine APOTEX 500 mg tablet (blister pack):
AUST R 202738

Sponsor

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