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

This leaflet answers some common questions about this medicine. 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

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).

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.

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.

There is no evidence that this medicine is addictive.

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

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 take this medicine

When you must not use it

Do not take this medicine if you have an allergy to:

- capecitabine
- 5-fluorouracil (also called 5-FU)
- 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 have any of the following medical conditions:

- severe kidney disease
- dihydropyramidine dehydrogenase (DPD) deficiency

Do not take this medicine if 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.

Do not take this medicine if you are 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.

Do not breastfeed if you are taking this medicine.

It is not known whether capecitabine and 5-FU pass into breast milk and there is a possibility that your baby may be affected.

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
- liver disease
- kidney disease
- dehydration

Some signs and symptoms of dehydration include:

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

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

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

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 capecitabine may interfere with each other. These include:

- medicines used to thin the blood such as warfarin and phenprocoumon
- phenytoin, used to treat epilepsy and heart irregularities
- leucovorin, also called folinic acid, used to treat folic acid deficient anaemias
- antacids, 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 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.

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.

Capecitabine 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 capecitabine therapy, where you will take capecitabine for 14 days, followed by a rest period of 7 days.

During the rest period, you will not take any capecitabine.

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

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

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)

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 of this medicine. 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

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

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.

Things you must not do

Do not take this medicine 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.

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.

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.

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

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

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)
- passing little or no urine (this could be kidney disease) – other symptoms include drowsiness, nausea, vomiting and breathlessness

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, disorientation or memory loss
- poor balance or lack of coordination
- decreased strength or progressive weakness in your body, numbness or weakness of arms or legs
- blurred or loss of vision
- 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
- symptoms of an allergic reaction including 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

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.

Some of these side effects, for example changes in triglycerides, can only be found when your doctor does tests from time to time to check your progress.

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

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. AUST R 202726.

Blister packs of 60 tablets.

Capecitabine APOTEX 500 mg tablets: Peach, oval, biconvex, film-coated tablet, engraved "APO" on one side, "C500" on the other side. AUST R 202738.

Blister packs of 120 tablets.

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

Ingredients

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

They also contain the following inactive ingredients:

- lactose
- croscarmellose sodium
- methylcellulose
- magnesium stearate
- colloidal anhydrous silica
- hypromellose
- hyprolose
- macrogol 8000
- titanium dioxide
- iron oxide red
- iron oxide yellow

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

Sponsor

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Australia

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