

NEW ZEALAND CONSUMER MEDICINE INFORMATION

CAPECITABINE VIATRIS



Capecitabine Film Coated Tablets 150 mg and 500 mg

What is in this leaflet

Please read this leaflet carefully before you start taking CAPECITABINE VIATRIS.

This leaflet answers some common questions about CAPECITABINE VIATRIS.

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 CAPECITABINE VIATRIS 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 CAPECITABINE VIATRIS is used for

CAPECITABINE VIATRIS 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.

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

CAPECITABINE VIATRIS contains the active ingredient Capecitabine.

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 this medicine for another reason.

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

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

Before you take CAPECITABINE VIATRIS

When you must not take it

Do not take CAPECITABINE VIATRIS if you have an allergy to:

- any medicine containing Capecitabine
- 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 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.

CAPECITABINE VIATRIS may be harmful to an unborn baby when

taken by a pregnant woman. It is not recommended that you take CAPECITABINE VIATRIS while you are pregnant. Additionally, if you are a woman, you should use effective contraception to avoid becoming pregnant while you are taking CAPECITABINE VIATRIS.

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

It is not known whether CAPECITABINE VIATRIS and 2-FU pass into breast milk. There is a possibility that your baby may be affected.

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 a severe kidney disease.

Do not take this medicine if you have severe neutropenia (low level of white blood cells called neutrophils), thrombocytopenia (low level of platelets) or leukopenia (low white blood cell count).

Do not take this medicine if you have severe liver impairment.

Do not take this medicine if you have known complete dihydropyrimidine dehydrogenase (DPD) deficiency.

Do not take this medicine if you are taking a medicine containing sorivudine or brivudine.

Taking sorivudine or brivudine at the same time as CAPECITABINE VIATRIS 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
- Liver disease
- Kidney disease

Tell your doctor if you are dehydrated.

Some signs and symptoms of dehydration include:

- Dry skin
- Dark coloured urine
- Thirst
- Weakness or fatigue
- Loss of appetite

Tell your doctor if you plan to have surgery.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

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

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking CAPECITABINE VIATRIS.

Some medicines may interfere with CAPECITABINE VIATRIS. These include:

- Warfarin, a medicine used to thin the blood
- 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
- Allopurinol, a medicine used to prevent gout attacks or flares

These medicines may be affected by CAPECITABINE VIATRIS 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 CAPECITABINE VIATRIS

How much to take

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

They may differ from the information contained in this leaflet. CAPECITABINE VIATRIS may be given with or without chemotherapy. Your doctor will tell you how many CAPECITABINE VIATRIS 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 CAPECITABINE VIATRIS.

Use in Elderly

The same dose is recommended for elderly patients given CAPECITABINE VIATRIS alone. A lower dose may be given to elderly patients taking CAPECITABINE VIATRIS in combination with other medicines to treat cancer. Please follow your doctor's instructions carefully.

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

How to take it

CAPECITABINE VIATRIS should be swallowed whole with water 30 minutes after a meal. Do not chew the tablets.

When to take it

Take CAPECITABINE VIATRIS tablets twice daily (morning and evening).

Take CAPECITABINE VIATRIS 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 CAPECITABINE VIATRIS should be taken.

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

How long to take it

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

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

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

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

If you forget to take it

Do not take an extra dose. Wait until the next dose and take your normal dose then.

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

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.

While you are taking CAPECITABINE VIATRIS

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking CAPECITABINE VIATRIS.

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 while taking this medicine, stop taking it and tell your doctor immediately.

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

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

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

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

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

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

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

CAPECITABINE VIATRIS 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.

CAPECITABINE VIATRIS 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.

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 of 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.

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.

Things you must not do

Do not take CAPECITABINE VIATRIS 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 change the dosage without checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

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 VIATRIS affects you.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much CAPECITABINE VIATRIS. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include:

- Nausea
- Vomiting
- Diarrhoea
- Stomach upset or irritations
- Bleeding
- Inflammation of the mouth

Side effects

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

This medicine helps most people with bowel cancer, breast cancer, stomach cancer and cancer of the oesophagus (food pipe), 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 treatment if you get some of the side effects.

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), 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

The above list includes the more common side effects of your medicine. Your doctor will tell you more about them. Your doctor may also recommend that you change the dose of CAPECITABINE VIATRIS that you are taking if you experience any of the above side effects.

Tell your doctor immediately and stop taking CAPECITABINE VIATRIS 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)

The above list includes serious side effects that may require medical attention. You need to stop taking CAPECITABINE VIATRIS if you experience the above side effects. Your doctor will treat your side effects before they start you on CAPECITABINE VIATRIS 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 heartbeat
- 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

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

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

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some people and there may be some side effects not yet known. Tell your doctor if you notice any other effects.

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

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

VIATRIS with a chemotherapy medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking CAPECITABINE VIATRIS

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 CAPECITABINE VIATRIS 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

CAPECITABINE VIATRIS 150 mg Film-coated Tablets

Light peach coloured, oblong shaped, biconvex, film-coated tablets, debossed with "150" on one side and plain on the other side.

CAPECITABINE VIATRIS 500 mg Film-coated Tablets

Peach coloured, oblong shaped, biconvex, film-coated tablets,

debossed with "500" on one side and plain on the other side.

Ingredients

Active ingredient:

CAPECITABINE VIATRIS contains 150 mg or 500 mg of Capecitabine as the active ingredient.

Inactive ingredients:

CAPECITABINE VIATRIS also contains:

- lactose
- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- hypromellose
- talc
- titanium dioxide
- ferric oxide red
- ferric oxide yellow.

Contains sugars as lactose.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

CAPECITABINE VIATRIS is supplied in New Zealand by:

Viatris Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

Date of Preparation

14 February 2023
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