CAPECITABINE WINTHROP®
Capecitabine
150mg and 500mg film-coated tablets

Consumer medicine information

What is in this leaflet
This leaflet answers some common questions about Capecitabine Winthrop 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 Capecitabine Winthrop 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 Capecitabine Winthrop is used for
Capecitabine Winthrop contains the active ingredient capecitabine.

Capecitabine Winthrop belongs to a class of medicines called fluoropyrimidine analogues. Capecitabine Winthrop is used to treat cancer of the bowel and rectum (colorectal), oesophagus, stomach and breast. It may be prescribed alone or in combination with other medicines used to treat cancer.

The medicine contained in Capecitabine Winthrop tablets, capecitabine, is converted by liver and cancer cells to another substance 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 Capecitabine Winthrop for another purpose.

Ask your doctor if you have any questions about why Capecitabine Winthrop has been prescribed for you.

This medicine is available only with a doctor’s prescription. Capecitabine Winthrop is not addictive.

Before you take it

When you must not take it
Do not take Capecitabine Winthrop if:

1) you have had an allergy to
   • capecitabine or any of the ingredients listed at the end of this leaflet
   • 5-fluorouracil (also known as 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, hives on the skin

2) you have severe kidney disease

3) you are taking a medicine containing sorivudine or brivudine

Taking sorivudine or brivudine at the same time as
Capecitabine Winthrop is potentially fatal.

4) the package is torn or shows signs of tampering

5) 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 Capecitabine Winthrop, talk to your doctor.

**Use in children**
Do not give Capecitabine Winthrop 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 Capecitabine Winthrop.
Tell your doctor if:

1) you are pregnant or plan to become pregnant

Capecitabine Winthrop may be harmful to an unborn baby when taken by a pregnant woman. It is not recommended that you take Capecitabine Winthrop while you are pregnant. Additionally, if you are a woman, you should use effective contraception to avoid becoming pregnant while you are taking Capecitabine Winthrop.

2) you are breast-feeding or plan to breast-feed

It is not known whether Capecitabine Winthrop passes into breast milk. Your doctor will discuss the risks and benefits of you taking Capecitabine Winthrop if you are breast-feeding.

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

- known dihydropyrimidine dehydrogenase (DPD) deficiency
- 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 Capecitabine Winthrop.

**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 health food shop.

Some medicines may interfere with Capecitabine Winthrop.

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 folinic acid, a medicine used to treat folic acid deficient anemias
- antacids, medicines used to treat heartburn or indigestion

These medicines may be affected by Capecitabine Winthrop, or may affect how well it 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 Capecitabine Winthrop.

**How to take Capecitabine Winthrop**

**How much to take**
Take Capecitabine Winthrop exactly as your doctor has prescribed.

Capecitabine Winthrop may be given with or without chemotherapy.

Your doctor will tell you how many Capecitabine Winthrop 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) and 500 mg (peach) 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 Winthrop.

Use in elderly
The same dose is recommended for elderly patients given Capecitabine Winthrop alone. A lower dose may be given to elderly patients taking Capecitabine Winthrop 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 Capecitabine Winthrop tablets twice a day (morning and evening).
Capecitabine Winthrop tablets should be taken with food. You should take Capecitabine Winthrop no later than 30 minutes after food.
Take Capecitabine Winthrop 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 Winthrop should be taken.
If you are not sure when to take Capecitabine Winthrop, ask your doctor.

How long to take Capecitabine Winthrop
The duration of treatment with Capecitabine Winthrop varies, depending on the nature of your illness and your individual response to the treatment.
Your Capecitabine Winthrop 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 will consist of intermittent Capecitabine Winthrop therapy, where you will take Capecitabine Winthrop for 14 days, followed by a rest period of 7 days. During the rest period, you will not take any Capecitabine Winthrop. Alternatively, your treatment cycle may be continuous which involves 21 days of Capecitabine Winthrop treatment and no rest period.
Continue taking Capecitabine Winthrop until your doctor tells you to stop.

If you forget to take Capecitabine Winthrop
Do not take an extra dose. Wait until the next dose and take Capecitabine Winthrop as you would normally.
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 Poisons Information Centre (New Zealand telephone 0800 764 766) for advice or go to your nearest Accident and Emergency centre if you think that you or anyone else may have taken too much Capecitabine Winthrop.
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 Capecitabine Winthrop

Things you must do
Tell all doctors, dentists and pharmacists who are treating you that you are taking Capecitabine Winthrop.
Tell your doctor if you become pregnant while taking Capecitabine Winthrop.
Tell your doctor immediately if you develop diarrhoea (more than 4 bowel movements each day).
Capecitabine Winthrop can sometimes cause diarrhoea in some people. Your doctor may stop your Capecitabine Winthrop treatment and treat your diarrhoea before starting
you on Capecitabine Winthrop tablets again.

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

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

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

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

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

Capecitabine Winthrop can cause redness and swelling of hands and/or feet that can affect your normal activities. Your doctor may decide to stop your Capecitabine Winthrop treatment until the side effect settles.

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

Capecitabine Winthrop 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 Winthrop 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 Capecitabine Winthrop 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 Capecitabine Winthrop 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 Winthrop affects you.

**Side effects**

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

Capecitabine Winthrop helps people with bowel or rectum 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), 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

These are the more common side effects of Capecitabine Winthrop. Your doctor will tell you more about them. Your doctor may also recommend that you change the dose of Capecitabine Winthrop that you are taking if you experience any of the above side effects.

Tell your doctor immediately and stop taking Capecitabine Winthrop 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 Capecitabine Winthrop if you experience the above side effects. Your doctor will treat your side effects before they start you on Capecitabine Winthrop 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
• 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 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
• severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
• severe skin reaction which starts with painful red areas, which become 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 Capecitabine Winthrop in combination with a chemotherapy medicine.

Please consult your doctor for possible side effects that may be casued by taking Capecitabine Winthrop 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.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking Capecitabine Winthrop

Storage

Keep your tablets in their package until it is time to take them.

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

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

**Product description**

**Availability**
Capecitabine Winthrop is available in two strengths, 150 mg and 500 mg.

Capecitabine Winthrop comes in blister packs in the following pack sizes:
- 150 mg – 60 and 200 tablets
- 500 mg – 120 and 200 tablets

**What Capecitabine Winthrop looks like**
- Capecitabine Winthrop 150 mg tablets are light peach coloured and oval shaped. They are engraved with “150” on one side.
- Capecitabine Winthrop 500 mg tablets are peach coloured and oblong capsule shaped. They are engraved with “500” on one side.

**Ingredients**

**Active ingredient**
capecitabine

**Inactive ingredients**
- croscarmellose sodium
- hypromellose
- microcrystalline cellulose
- silica colloidal anhydrous
- magnesium stearate

The tablets have a film-coating which contains:
- hypromellose
- talc
- titanium dioxide
- macrogol 400
- iron oxide yellow (E172)
- iron oxide red (E172)

Capecitabine Winthrop tablets are gluten free.

**Distributor**

Capecitabine Winthrop is supplied in New Zealand by:
sanofi-aventis new zealand limited
Level 8, James & Wells Tower
56 Cawley Street
Ellerslie
Auckland
Medical information (toll free): 0800 283 684
Email: medinfo.australia@sanofi.com

This leaflet was prepared on 10 Jun 2015