

# Capecitabine Sandoz®

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Capecitabine Sandoz?

Capecitabine Sandoz contains the active ingredient capecitabine. Capecitabine Sandoz 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. For more information, see Section [1. Why am I using Capecitabine Sandoz?](#) in the full CMI.

### 2. What should I know before I use Capecitabine Sandoz?

Do not use if you have ever had an allergic reaction to capecitabine or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Capecitabine Sandoz?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Capecitabine Sandoz and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Capecitabine Sandoz?

- Take Capecitabine Sandoz exactly as your doctor has prescribed.
- Capecitabine Sandoz may be given with or without chemotherapy. Your doctor will tell you how many Capecitabine Sandoz tablets to take each day and how often to take them. Your doctor will calculate the dose based on your height and weight. Capecitabine Sandoz tablets should be swallowed with water within 30 minutes after the end of a meal.

More instructions can be found in Section [4. How do I use Capecitabine Sandoz?](#) in the full CMI.

### 5. What should I know while using Capecitabine Sandoz?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or you visit that you are using Capecitabine Sandoz.</li><li>• Be sure to keep all of your appointments with your doctor so that your progress can be checked.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking Capecitabine Sandoz or change the dose without first checking with your doctor.</li><li>• Do not let yourself run out of medicine over the weekend or on holidays.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how Capecitabine Sandoz affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in their container until it is time to take them. If you take the tablets out of their container they may not keep well.</li><li>• Keep Capecitabine Sandoz in a cool dry place where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while using Capecitabine Sandoz?](#) in the full CMI.

### 6. Are there any side effects?

**Common side effects:** diarrhoea, vomiting, nausea, fatigue, weakness or weariness, skin rashes, dry or itchy skin, fever, dizziness, loss of appetite, weight loss, hair loss, increased eye watering or irritation, conjunctivitis.

**Severe side effects:**

- 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).

**Tell your doctor immediately and stop taking Capecitabine Sandoz if you notice any of the above.** For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Capecitabine Sandoz®

Active ingredient(s): *capecitabine*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Capecitabine Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Capecitabine Sandoz.**

**Where to find information in this leaflet:**

- [1. Why am I using Capecitabine Sandoz?](#)
- [2. What should I know before I use Capecitabine Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Capecitabine Sandoz?](#)
- [5. What should I know while using Capecitabine Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Capecitabine Sandoz?

**Capecitabine Sandoz contains the active ingredient capecitabine.** Capecitabine Sandoz belongs to a group of medicines called anti-neoplastic agents. Within this group, Capecitabine Sandoz belongs to a class of medicines called fluoropyrimidine analogues.

**Capecitabine Sandoz 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.**

The medicine contained in Capecitabine Sandoz tablets, 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 Capecitabine Sandoz for another purpose.

**Ask your doctor if you have any questions why Capecitabine Sandoz has been prescribed for you.**

Capecitabine Sandoz is not addictive.

## 2. What should I know before I use Capecitabine Sandoz?

### Warnings

**Do not use Capecitabine Sandoz if:**

- you are allergic to capecitabine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

- you are allergic to 5-fluorouracil (also called 5-FU), a medicine used to treat cancer
- you are allergic to other fluoropyrimidine medicines  
Some symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or difficulty in breathing
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching, hives on the skin
- you have severe kidney disease
- you have known dihydropyrimidine dehydrogenase (DPD) deficiency
- you are taking a medicine containing sorivudine or brivudine. Taking sorivudine or brivudine at the same time as Capecitabine Sandoz is potentially fatal.
- you have low white blood cells (frequent infections such as fever, severe chills, sore throat or mouth ulcers) and low blood platelet count (bleeding or bruising more easily than normal).
- you have liver problems.
- the package is torn or shows signs of tampering
- 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.

### Check with your doctor if you:

- have any other medical conditions, especially the following:
  - heart disease
  - liver disease
  - kidney disease
  - sugar in the blood
  - unbalanced electrolytes
  - low or high level of calcium
  - poor balance or lack of coordination
  - numbness or weakness of the hands or feet
  - history of eye disorders
- take any medicines for any other condition
- are dehydrated. Some signs and symptoms of dehydration include dry skin, dark coloured urine, thirst, weakness or fatigue, and loss of appetite.
- are allergic to any other medicines, foods, dyes or preservatives.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

**Do not take Capecitabine Sandoz if you are pregnant.**

Capecitabine Sandoz may be harmful to an unborn baby when taken by a pregnant woman. It is not recommended that you take Capecitabine Sandoz while you are pregnant.

Additionally, if you are a woman, you should use effective contraception to avoid becoming pregnant while you are taking Capecitabine Sandoz.

### **Do not breast-feed if you are taking Capecitabine Sandoz.**

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

### **Use in children**

#### **Do not give Capecitabine Sandoz to children.**

Safety and effectiveness in persons less than 18 years of age have not been established.

## **3. What if I am taking other medicines?**

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

#### **Some medicines may interfere with Capecitabine Sandoz. 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 anaemias
- antacids, medicines used to treat heart burn or indigestion
- allopurinol, a medicine used to treat excess uric acid levels in blood.

These medicines may be affected by Capecitabine Sandoz or may affect how well Capecitabine Sandoz works. You may need to use different amounts of your medicines or take different medicines. Your doctor will advise you.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Capecitabine Sandoz.**

## **4. How do I use Capecitabine Sandoz?**

### **How much to take**

- **Take Capecitabine Sandoz exactly as your doctor has prescribed.**
- Capecitabine Sandoz may be given with or without chemotherapy. Your doctor will tell you how many Capecitabine Sandoz 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 (pink coloured with 150 mg embossed) and 500 mg (pink coloured with 500 mg embossed) 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 Sandoz. Elderly patients may need to receive less.

### **Use in elderly**

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

### **When to take Capecitabine Sandoz**

- **Take Capecitabine Sandoz tablets twice a day (morning and evening).**
- **Capecitabine Sandoz tablets should be taken with food. You should take Capecitabine Sandoz no later than 30 minutes after food.**
- **Take Capecitabine Sandoz 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 Sandoz should be taken.
- **If you are not sure when to take Capecitabine Sandoz, ask your doctor.**

### **How to take Capecitabine Sandoz**

- **Swallow the tablets whole with a glass of water.**
- **Do not chew the tablets.**

### **How long to take Capecitabine Sandoz**

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

### **If you forget to use Capecitabine Sandoz**

Capecitabine Sandoz should be used regularly at the same time each day. If you miss your dose at the usual time, 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 you missed.**

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

### If you use too much Capecitabine Sandoz

If you think that you have used too much Capecitabine Sandoz, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

## 5. What should I know while using Capecitabine Sandoz?

### Things you should do

Call your doctor straight away if you:

- **become pregnant while taking Capecitabine Sandoz.**
- **develop diarrhoea (more than 4 bowel movements each day).** Capecitabine Sandoz can sometimes cause diarrhoea in some people. Your doctor may stop your Capecitabine Sandoz treatment and treat your diarrhoea before starting you on Capecitabine Sandoz tablets again.
- **develop nausea (feeling like you want to vomit) and it has affected your appetite significantly.** Capecitabine Sandoz can cause nausea in some people. Your doctor may stop your Capecitabine Sandoz treatment and treat your nausea before starting you on Capecitabine Sandoz tablets again.
- **develop vomiting and vomit more than once in a 24 hour period.** Capecitabine Sandoz can cause vomiting in some people. Your doctor may stop your Capecitabine Sandoz treatment and treat your vomiting before starting you on Capecitabine Sandoz tablets again.
- **develop redness or swelling of your hands and/or feet that affects your normal activities.** Capecitabine Sandoz 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 Sandoz treatment until the side effect settles.
- **develop pain, redness, swelling or sores in the mouth.** Capecitabine Sandoz 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 Sandoz treatment until the side effect settles.
- **have not taken your medicine exactly as prescribed.** Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.
- **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.

Remind any doctor, dentist or pharmacist you visit that you are using Capecitabine Sandoz.

### Things you should not do

**Do not stop taking Capecitabine Sandoz 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 Sandoz 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.**

### Driving or using machines

Be careful before you drive or use any machines or tools until you know how Capecitabine Sandoz affects you.

### Looking after your medicine

- Keep your tablets in their container until it is time to take them. If you take the tablets out of their container they may not keep well.
- Keep Capecitabine Sandoz in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Gastro-intestinal:</b> <ul style="list-style-type: none"><li>• diarrhoea</li><li>• vomiting</li><li>• nausea (feeling like you want to vomit)</li><li>• abdominal (gut) pain</li><li>• constipation</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<ul style="list-style-type: none"> <li>• indigestion, wind</li> <li>• dry mouth, thirst</li> <li>• sore mouth, mouth ulcers, cold sores</li> </ul> <p><b>General Disorders:</b></p> <ul style="list-style-type: none"> <li>• fatigue (tiredness), weakness or weariness</li> <li>• fever, or increased temperature sensitivity</li> <li>• headache</li> <li>• dizziness</li> <li>• taste disturbance</li> <li>• difficulty sleeping</li> </ul> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>• skin rashes, dry or itchy skin</li> <li>• hair loss</li> <li>• nail disorders</li> <li>• redness or swelling of your hands and/or feet</li> </ul> <p><b>Metabolism related:</b></p> <ul style="list-style-type: none"> <li>• loss of appetite, weight loss</li> </ul> <p><b>Eye related:</b></p> <ul style="list-style-type: none"> <li>• increased eye watering or irritation, conjunctivitis (itchy eyes and crusty eyelids)</li> </ul> <p><b>Respiratory related:</b></p> <ul style="list-style-type: none"> <li>• shortness of breath, difficulty in breathing, or tightening of the chest</li> <li>• sore throat, cough, nose bleeds</li> </ul> <p><b>Others:</b></p> <ul style="list-style-type: none"> <li>• tingling or numbness of the hands or feet</li> <li>• muscle and joint pain</li> <li>• dark coloured urine</li> </ul>	
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These are the more common side effects of Capecitabine Sandoz that you are likely to notice. Your doctor will tell you more about them. Your doctor may also recommend that you change the dose of Capecitabine Sandoz that you are taking if you experience any of the above side effects.

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• chest pain</li> <li>• irregular heart beat</li> <li>• shortness of breath</li> <li>• 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</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</b></p>

<ul style="list-style-type: none"> <li>• poor balance or lack of co-ordination</li> <li>• numbness or weakness of arms or legs</li> <li>• signs of infection such as swelling, redness and increased temperature</li> <li>• signs of liver disease such as yellowing of the skin and eyes</li> <li>• blood in the faeces</li> <li>• severe blisters and bleeding in the lips, eyes, mouth, nose and genitals</li> <li>• 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.</li> </ul>	<p><b>these serious side effects.</b></p>
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These are serious side effects. You may need urgent medical attention.

### Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> <li>• severe diarrhoea with more than 4 bowel movements each day</li> <li>• nausea that has reduced your appetite significantly</li> <li>• vomiting more than once in a 24 hour period</li> <li>• pain, redness and/or swelling of your hands and/or feet that has affected your normal activities (hand-foot-syndrome)</li> <li>• pain, redness, swelling or ulcers in the mouth (stomatitis)</li> </ul>	<p><b>Stop taking Capecitabine Sandoz and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b></p>

You need to stop taking Capecitabine Sandoz if you experience the above side effects. Your doctor will treat your side effects before they start you on Capecitabine Sandoz again.

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 Sandoz in combination with a chemotherapy medicine.

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

### Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

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## 7. Product details

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

### What Capecitabine Sandoz contains

<b>Active ingredient (main ingredient)</b>	capecitabine
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate croscarmellose sodium hypromellose microcrystalline cellulose magnesium stearate hypromellose purified talc titanium dioxide iron oxide red
<b>Potential allergens</b>	lactose monohydrate

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Capecitabine Sandoz looks like

Capecitabine Sandoz is available in two strengths, 150 mg and 500 mg.

Capecitabine Sandoz 150 mg – light pink coloured, modified oval shaped film-coated tablets with '150' marked on one side. Available in blister packs of 60 tablets (AUST R 201797).

Capecitabine Sandoz 500 mg – pink coloured, modified oval shaped film-coated tablets with '500' marked on one side. Available in blister packs of 120 tablets (AUST R 201800).

*Not all strengths may be marketed in Australia.*

### Who distributes Capecitabine Sandoz

Sandoz Pty Ltd  
100 Pacific Highway  
North Sydney, NSW 2060  
Australia  
Tel 1800 726 369

This leaflet was prepared in November 2025.