

CAPECITABINE SANDOZ®

Capecitabine tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CAPECITABINE SANDOZ 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 SANDOZ 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 SANDOZ is used for

CAPECITABINE SANDOZ contains the active ingredient capecitabine.

CAPECITABINE SANDOZ belongs to a group of medicines called antineoplastic 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.

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

CAPECITABINE SANDOZ is not addictive.

Before you take CAPECITABINE SANDOZ

When you must not take it

Do not take CAPECITABINE SANDOZ if:

- 1. you have had an allergy 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.**

Some of the 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.

- 2. if you have severe kidney disease**
- 3. if you have known dihydropyrimidine dehydrogenase (DPD) deficiency**
- 4. you are taking a medicine containing sorivudine or brivudine**

Taking sorivudine or brivudine at the same time as CAPECITABINE SANDOZ is potentially fatal.
- 5. the package is torn or shows signs of tampering**
- 6. 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.

Do not take CAPECITABINE SANDOZ if you are pregnant.

Do not breast-feed if you are taking CAPECITABINE SANDOZ.

Do not take CAPECITABINE SANDOZ if 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).

Do not take CAPECITABINE SANDOZ if you have liver problems.

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

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.

Before you start to take it

Your doctor must know about all the following before you start to take CAPECITABINE SANDOZ.

Tell your doctor if:

- 1. you are pregnant or plan to become 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.
- 2. you are breast-feeding or plan to breast-feed**
It is not known whether CAPECITABINE SANDOZ and 5-FU pass into breast milk. You doctor will discuss the risks and benefits of you taking CAPECITABINE SANDOZ if you are breast-feeding.
- 3. you have any other health problems, 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.**
- 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 SANDOZ.

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 healthfood 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 folic 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.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking CAPECITABINE SANDOZ.

How to take 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.

How to take it

Swallow the tablets whole with a glass of water.

Do not chew the tablets.

When to take it

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 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 take CAPECITABINE SANDOZ

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

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 the Poisons Information Centre (Australia telephone 13 11 26; New Zealand telephone 0800 764 766) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much CAPECITABINE SANDOZ.

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 SANDOZ

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking CAPECITABINE SANDOZ.

Tell your doctor if you become pregnant while taking CAPECITABINE SANDOZ.

Tell your doctor immediately if you 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.

Tell your doctor immediately if you 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.

Tell your doctor immediately if you 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.

Tell your doctor immediately if you 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.

Tell your doctor immediately if you 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.

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 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.

Things to be careful of

Be careful driving or operating machinery until you know how CAPECITABINE SANDOZ affects you.

Side effects

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

CAPECITABINE SANDOZ helps people with bowel 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 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.

Tell your doctor immediately and stop taking CAPECITABINE SANDOZ 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 SANDOZ if you experience the above side effects. Your doctor will treat your side effects before they start you on CAPECITABINE SANDOZ 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
- shortness of breath
- 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, then 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 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 if you notice anything else that is making you feel unwell, even if it is not on this list.

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

You may not experience any of them.

After taking CAPECITABINE SANDOZ

Storage

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.

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 SANDOZ 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 SANDOZ, 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 SANDOZ is available in two strengths, 150 mg and 500 mg.

CAPECITABINE SANDOZ comes in blister packs in the following pack sizes:

- 150 mg - 60 tablets
- 500 mg - 120 tablets

What CAPECITABINE SANDOZ looks like

- CAPECITABINE SANDOZ 150 mg tablets are light pink coloured and oblong-shaped. They are engraved with "150".
- CAPECITABINE SANDOZ 500 mg tablets are pink coloured and oblong-shaped. They are engraved with "500".

Ingredients

Active ingredient

- capecitabine.

Inactive ingredients

- lactose
- croscarmellose sodium
- hypromellose
- microcrystalline cellulose
- magnesium stearate.

The tablets have a film-coating which contains:

- hypromellose
- talc
- titanium dioxide
- iron oxide red (CI77491).

CAPECITABINE SANDOZ tablets are gluten free.

Distributor

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road,
Macquarie Park, NSW 2113
AUSTRALIA
Tel: 1800 634 500

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