PART III: CONSUMER INFORMATION

[Pr] Sandoz Capecitabine
Capecitabine Tablets
150 mg and 500 mg

This leaflet is part III of a three-part "Product Monograph" published when Sandoz Capecitabine was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Sandoz Capecitabine. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
Sandoz Capecitabine is a prescription medication that is used to treat the following types of cancer:

Adjuvant therapy, stage III colon cancer
Sandoz Capecitabine is used to treat cancer of the colon following complete surgical removal. The intent of treatment with Sandoz Capecitabine is to prevent or delay the recurrence of cancer (cure).

Advanced or metastatic cancer
Sandoz Capecitabine is used to treat *advanced or metastatic breast cancer*. Metastatic means that the cancer has spread outside the breast. When breast cancer has not responded to other chemotherapy medications, Sandoz Capecitabine may be one of the choices considered for treatment. Your doctor may prescribe Sandoz Capecitabine either alone or in combination with a chemotherapy drug called Taxotere® (also known as docetaxel).

Sandoz Capecitabine is also used to treat *metastatic colorectal cancer* that has spread outside of the colon and/or rectum. Sandoz Capecitabine may be one of the choices considered for treatment. Your doctor may prescribe Sandoz Capecitabine either alone or in combination with a chemotherapy drug called Eloxatin® (also known as oxaliplatin).

What it does:
Sandoz Capecitabine belongs to a family of medications called the fluoropyrimidines. These medications interfere with the growth of cells that rapidly divide in the body, including cancer cells. Sandoz Capecitabine is an inactive substance on its own. When Sandoz Capecitabine is taken, it is changed in the body, mostly within the tumour (cancer cells). It changes to become the commonly used cancer medication called 5-fluorouracil (also known as 5-FU). In some patients 5-FU will kill cancer cells and decrease the size of the tumour.

When it should not be used:
- If you are allergic to the medicinal ingredient (capecitabine) or to 5-fluorouracil.
- If you are allergic to any of the other non-medicinal ingredients it contains (see 'What the non-medicinal ingredients are')
- If you suffer from severe kidney disease
- Your body does not have the enzyme DPD (dihydropyrimidine dehydrogenase)
- If you are being treated now or have been treated in the last 4 weeks with brivudine, sorivudine or similar classes of substance[1] as part of herpes zoster (chickenpox or shingles) therapy.

What the medicinal ingredient is:
capecitabine

What the important nonmedicinal ingredients are:
Sandoz Capecitabine tablets contain the following non-medicinal ingredients:
Croscarmellose sodium, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, red iron oxide, talc, titanium dioxide.

What dosage forms it comes in:
150 mg and 500 mg tablets.

Sandoz Capecitabine 150 mg tablets are light pink-coloured, modified oval shaped tablets with debossment "150" on side. Sandoz Capecitabine 150 mg tablets are available in blister packs containing 60 tablets (10 tablets per blister card and 6 blister cards per carton).

Sandoz Capecitabine 500 mg tablets are pink-coloured, modified oval shaped tablets with debossment "500" on side. Sandoz Capecitabine 500 mg tablets are available in blister packs containing 120 tablets (10 tablets per blister card and 12 blister cards per carton).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
Serious side effects include:
- **Severe dehydration may cause rapid loss of kidney functions including kidney failure that may lead to death.**
- **Similar to other cancer medicines of the same class, toxicity that may lead to sudden death due to heart problems including irregular heartbeat.**
- **Severe skin reactions such as hand-and foot syndrome, Stevens-Johnson Syndrome [SJS] and Toxic Epidermal Necrolysis [TEN].**
- **Rarely, unexpected, severe toxicity due to 5-FU has been associated with dihydropyrimidine dehydrogenase (DPD) deficiency.**
- **Increased action of other medicines used to thin your blood such as warfarin leading to serious side effects.**

BEFORE you use Sandoz Capecitabine talk to your doctor or pharmacist if:

- you ever had a bad reaction to capecitabine, 5-FU or any of the non-medicinal ingredients.
- you are allergic to other medications, food and dyes.

[1] sorivudine and its chemically related analogues, such as brivudine are not approved in Canada.

- you have been told you lack the DPD enzyme.
- you are taking any other medications, including those not prescribed by your doctor.
- you are taking warfarin (Coumadin®). Your doctor may need to check the clotting time of your blood more often.
- you are taking phenytoin (Dilantin®) or fosphenytoin (Cerebyx®). Your doctor may need to check the levels of phenytoin in your blood more often.
- you have any other illnesses or diseases affecting your kidneys, liver or heart.
- you are pregnant, plan to become pregnant or are breastfeeding.

The safety and effectiveness of capecitabine in persons <18 years of age has not been established.

This information will help your doctor and you decide whether you should use Sandoz Capecitabine and what extra care may need to be taken while you are on the medication.

What else should you remember while you are taking Sandoz Capecitabine?

- Practice contraception: If you are of childbearing age you should avoid becoming pregnant while taking Sandoz Capecitabine. No research studies have been done with pregnant women. However, studies with animals suggest that capecitabine may cause serious harm to an unborn child.
- Practice contraception: If you are a male, you are advised not to father a child during treatment.
- You should stop breastfeeding if you start treatment with Sandoz Capecitabine.
- If you are over 65 years old or have a history of heart disease, you may be more sensitive to Sandoz Capecitabine. Watch more carefully for possible unwanted effects.
- If you are over 80 years old, your stomach may be more sensitive to Sandoz Capecitabine. Watch more carefully for possible unwanted effects.

If you experience persistent or severe hand-and-foot syndrome while taking Sandoz Capecitabine, it can eventually lead to loss of fingerprints, which could impact your identification by fingerprint scan.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Sandoz Capecitabine include:

- Medicine used to treat seizures (e.g. Phenytoin and Fosphenytoin)
- Blood thinner medicine (e.g. warfarin and phenprocoumon)
- Medicine used to treat heartburn and acid indigestion (e.g. Maalox®)
- Leucovorin, a medicine used to prevent the harmful effects of cancer chemotherapy medication
- Certain medicines used specifically for treating viral infections (e.g. sorivudine and brivudine[2])

[2] sorivudine and its chemically related analogues, such as brivudine are not approved in Canada.

PROPER USE OF THIS MEDICATION

Usual dose:

Your doctor prescribed Sandoz Capecitabine after carefully studying your condition. Other people may not benefit from taking this medicine, even though their problems may seem similar to yours. Do not give your Sandoz Capecitabine to anyone else.

The usual dose of Sandoz Capecitabine depends on your body surface size.

Your doctor will calculate the dose for you.

You may need to take a combination of 150 mg and 500 mg tablets. **To get the right dose it is very important that you identify the tablets correctly each time you take Sandoz Capecitabine.** Taking the wrong tablets could result in an overdose (too much medication) or underdose (too little medication).

Swallow the Sandoz Capecitabine tablets whole, with water. Take the tablets within 30 minutes after the end of a meal (breakfast and dinner). Take the tablets twice a day (morning and evening doses) as your doctor prescribed. Do not take more than your prescribed dose, do not take it more often or for a longer time than your doctor ordered.

Sandoz Capecitabine is taken in 21 day cycles. This means you take Sandoz Capecitabine for 14 days and then stop taking it for 7 days. It is important to have this rest period. Your doctor will decide how many cycles of treatment you will need.

For the treatment of colon cancer following complete surgical removal, Sandoz Capecitabine is usually taken for eight 21-day cycles (i.e. for a total of 24 weeks or approximately 6 months).

Overdose:

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget a dose of Sandoz Capecitabine do not take the missed dose at all. Take your next dose at the usual time and check with your doctor. Do not take a double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Unwanted effects are possible with all medicines. Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are taking Sandoz Capecitabine.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptoms / effects		**Talk with your doctor or pharmacist**		**Stop taking drug and seek immediate emergency medical attention**
		Only if severe	**In all cases**	
Very Common	diarrhea, sores in the mouth and throat (called stomatitis), tiredness or fatigue, nausea, vomiting, tingling, numbness, pain, swelling, redness or blisters of the palms of the hands or feet (called hand-and-foot syndrome)		✓	
Common	reduced white blood cells, red blood cells and platelets in the blood, increased chance of infection, increased chance of unusual bleeding, dehydration (increased thirst, dry or sticky mouth)		✓	
Rare	weakness, lack of energy, shortness of breath, confusion		✓	
Very Rare	severe skin reactions (redness, pain, swelling or blistering of lips, eyes or mouth, skin peeling and flu-like symptoms weakness of the legs and arms, drowsiness, generalized seizures, headaches, and vision impairment.		✓	

Stop taking Sandoz Capecitabine and call your doctor immediately if you notice any of the following side effects. Your doctor can then adjust Sandoz Capecitabine to a dose that is right for you. This should help to reduce the side effects and stop them from getting worse.

Diarrhea
- an additional 4 bowel movements a day beyond what is normal or any diarrhea at night
- if you have a colostomy, an increase in loose, watery fluid in your colostomy bag
- any diarrhea in conjunction with soreness of the mouth affecting your ability to drink enough fluids

Vomiting
- vomiting more than once in 24 hours, especially if in association with diarrhea

Nausea
- loss of appetite or eating less food than usual each day

Stomatitis
- painful sores, redness or swelling in the mouth or throat

Hand-and-foot Syndrome
- pain, redness, swelling, ulcers or blisters on the hands and feet

Infection
- fever; a temperature of 38.0 °C or higher
- signs of infection such as sore throat, cough, or pain when you pass urine

Heart problems
- chest pains, abnormal heart rate, edema of extremities

Your doctor may tell you to decrease the dose or stop Sandoz Capecitabine treatment for a while. If caught early, most of these side effects usually improve after you stop taking Sandoz Capecitabine. If they do not improve within 2 to 3 days, call your doctor again. After side effects have improved, your doctor will tell you whether to start taking Sandoz Capecitabine again and what is the right dose for you.

These unwanted effects may differ when taking Sandoz Capecitabine in combination with Taxotere® (docetaxel). For example, in addition to the unwanted effects mentioned above which may occur with Sandoz Capecitabine alone, the following unwanted effects may occur when Sandoz Capecitabine is taken in combination with Taxotere®: hair loss, weakness, fluid retention, nail changes and peripheral neuropathy (numbness, tingling, and burning of the hands and feet), constipation, abdominal pain, indigestion, dry mouth, rash, weakness, pain, taste disturbance, headache, dizziness, inability to sleep, loss or decreased appetite, dehydration, back pain. Please consult your doctor for more information on the possible unwanted effects that may occur when taking Sandoz Capecitabine in combination with Taxotere® (docetaxel).

If you are concerned about these or any other unexpected effects while taking Sandoz Capecitabine, talk with your doctor, nurse or pharmacist.

This is not a complete list of side effects. For any unexpected

effects while taking Sandoz Capecitabine, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of reach of children.

Store at room temperature (15°C to 30°C), in the original labelled container or package.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 0701E
    Ottawa, ON
    K1A 0K9

  Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Sandoz Canada Inc., at:

1-800-361-3062

or by written request at:
145 Jules-Léger
Boucherville QC
J4B 7K8

Or by e-mail at:
medinfo@sandoz.com

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