PRODUCT MONOGRAPH

Pr XELODA®

capecitabine

Tablets 150 mg and 500 mg

Manufacturer's Standard

Antineoplastic Agent

Hoffmann-La Roche Limited
7070 Mississauga Road
Mississauga, Ontario
L5N 5M8

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www.rochecanada.com

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PART III: CONSUMER INFORMATION

Pr XELODA®
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This leaflet is part III of a three-part "Product Monograph" published when XELODA (pronounced zeh-LO-da) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about XELODA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

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

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

Advanced or metastatic cancer
XELODA 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, XELODA may be one of the choices considered for treatment. Your doctor may prescribe XELODA either alone or in combination with a chemotherapy drug called Taxotere® (also known as docetaxel).

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

What it does:
XELODA 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. XELODA is an inactive substance on its own. When XELODA 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 4weeks 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 non-medicinal ingredients are:
XELODA tablets contain the following non-medicinal ingredients:
croscarmellose sodium, hydroxypropyl methylcellulose, iron oxides (yellow and red), lactose anhydrous, magnesium stearate microcrystalline cellulose, talc, titanium dioxide.

What dosage forms it comes in:
XELODA is available as tablets that are taken by mouth. The tablets are coated and oblong shaped.

XELODA tablets come in two strengths:
150 mg tablets are light peach coloured, with XELODA engraved on one side and 150 on the other side. The 150 mg tablets are available in bottles containing 60 tablets or in blister packs containing 60 tablets (10 tablets per blister card and 6 blister cards per carton).

500 mg tablets that are peach coloured with XELODA engraved on one side and 500 on the other side. The 500 mg tablets are available in bottles containing 120 tablets or 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 XELODA 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.
- you have been told you lack the DPD enzyme.

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

- 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 XELODA in persons <18 years of age has not been established.

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

What else should you remember while you are taking XELODA?

- Practice contraception: If you are of childbearing age you should avoid becoming pregnant while taking XELODA. No research studies have been done with pregnant women. However, studies with animals suggest that XELODA 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 XELODA.
- If you are over 65 years old or have a history of heart disease, you may be more sensitive to XELODA. Watch more carefully for possible unwanted effects.
- If you are over 80 years old, your stomach may be more sensitive to XELODA. Watch more carefully for possible unwanted effects.

If you experience persistent or severe hand-and-foot syndrome while taking XELODA, 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 XELODA include:

- Medicine used to treat seizures (eg. Phenytoin and Fosphenytoin)
- Blood thinner medicine (eg. warfarin and phenprocoumon)
- Medicine used to treat heartburn and acid indigestion (eg.Maalox®)
- Leucovorin, a medicine used to prevent the harmful effects of cancer chemotherapy medication
- Certain medicines used specifically for treating viral infections (eg. 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 XELODA 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 XELODA to anyone else.

The usual dose of XELODA 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 XELODA.** Taking the wrong tablets could result in an overdose (too much medication) or underdose (too little medication).

Swallow the XELODA 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.

XELODA is taken in 21 day cycles. This means you take XELODA 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, XELODA 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 health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget a dose of XELODA 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 XELODA.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		**Talk with your doctor or pharmacist**		**Stop taking drug and call your doctor or pharmacist**
		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 XELODA and call your doctor immediately if you notice any of the following side effects. Your doctor can then adjust XELODA 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 XELODA treatment for a while. If caught early, most of these side effects usually improve after you stop taking XELODA. 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 XELODA again and what is the right dose for you.

These unwanted effects may differ when taking XELODA in combination with Taxotere® (docetaxel). For example, in addition to the unwanted effects mentioned above which may occur with XELODA alone, the following unwanted effects may occur when XELODA 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 XELODA in combination with Taxotere® (docetaxel).

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

This is not a complete list of side effects. For any unexpected effects while taking XELODA, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of reach of children.

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

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
  Health Canada
  Postal Locator 0701E
  Ottawa, Ontario
  K1A 0K9

  Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/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 at: www.rochecanada.com or by contacting the sponsor, Hoffmann-La Roche Limited, at: 1-800-762-4388.

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