

Patient Information

XELODA[®] (capecitabine) TABLETS

Rx only

Read this leaflet before you start taking XELODA[®] [zeh-LOE-duh] and each time you refill your prescription in case the information has changed. This leaflet contains important information about XELODA. However, this information does not take the place of talking with your doctor. This information cannot cover all possible risks and benefits of XELODA. Your doctor should always be your first choice for discussing your medical condition and this medicine.

What is XELODA?

XELODA is a medicine you take by mouth (orally). XELODA is changed in the body to 5-fluorouracil (5-FU). In some patients with colon, rectum or breast cancer, 5-FU stops cancer cells from growing and decreases the size of the tumor.

XELODA is used to treat:

- cancer of the colon after surgery
- cancer of the colon or rectum (colorectal cancer) that has spread to other parts of the body (metastatic colorectal cancer). You should know that in studies, other medicines showed improved survival when they were taken together with 5-FU and leucovorin. In studies, XELODA was no worse than 5-FU and leucovorin taken together but did not improve survival compared to these two medicines.
- breast cancer that has spread to other parts of the body (metastatic breast cancer) together with another medicine called docetaxel (TAXOTERE[®])
- breast cancer that has spread to other parts of the body and has not improved after treatment with other medicines such as paclitaxel (TAXOL[®]) and anthracycline-containing medicine such as Adriamycin[™] and doxorubicin

What is the most important information about XELODA?

XELODA may increase the effect of other medicines used to thin your blood such as warfarin (COUMADIN[®]). It is very important that your doctor knows if you are taking a blood thinner such as warfarin because XELODA may increase the effect of this medicine and could lead to serious side effects. If you are taking blood thinners and XELODA, your doctor needs to check more often how fast your blood clots and change the dose of the blood thinner, if needed.

Who should not take XELODA?

1. DO NOT TAKE XELODA IF YOU

- are nursing a baby. Tell your doctor if you are nursing. XELODA may pass to the baby in your milk and harm the baby.
- are allergic to 5-fluorouracil
- are allergic to capecitabine or to any of the ingredients in XELODA
- have been told that you lack the enzyme DPD (dihydropyrimidine dehydrogenase)

2. TELL YOUR DOCTOR IF YOU

- take a blood thinner such as warfarin (COUMADIN). This is very important because XELODA may increase the effect of the blood thinner. If you are taking blood thinners and XELODA, your doctor needs to check more often how fast your blood clots and change the dose of the blood thinner, if needed.
- take phenytoin (DILANTIN®). Your doctor needs to test the levels of phenytoin in your blood more often or change your dose of phenytoin.
- are pregnant or think you may be pregnant. XELODA may harm your unborn child.
- have kidney problems. Your doctor may prescribe a different medicine or lower the XELODA dose.
- have liver problems. You may need to be checked for liver problems while you take XELODA.
- have heart problems because you could have more side effects related to your heart.
- take the vitamin folic acid. It may affect how XELODA works.

How should I take XELODA?

Take XELODA exactly as your doctor tells you to. Your doctor will prescribe a dose and treatment plan that is right for *you*. Your doctor may want you to take both 150 mg and 500 mg tablets together for each dose. If so, you must be able to identify the tablets. Taking the wrong tablets could cause an overdose (too much medicine) or underdose (too little medicine). The 150 mg tablets are light peach in color with 150 on one side. The 500 mg tablets are peach in color with 500 on one side. Your doctor may change the amount of medicine you take during your treatment. Your doctor may prescribe XELODA Tablets with docetaxel (TAXOTERE) injection.

- XELODA is taken in 2 daily doses, a morning dose and an evening dose
- Take XELODA tablets **within 30 minutes after the end of a meal** (breakfast and dinner)
- **Swallow XELODA tablets whole with water**
- If you miss a dose of XELODA, do not take the missed dose at all and do not double the next dose. Instead, continue your regular dosing schedule and check with your doctor.
- XELODA is usually taken for 14 days followed by a 7-day rest period (no drug), for a 21-day cycle. Your doctor will tell you how many cycles of treatment you will need.
- If you take too much XELODA, contact your doctor or local poison control center or emergency room **right away**.

What should I avoid while taking XELODA?

- Women should not become pregnant while taking XELODA. XELODA may harm your unborn child. Use effective birth control while taking XELODA. Tell your doctor if you become pregnant.
- Do not breast-feed. XELODA may pass through your milk and harm your baby.
- Men should use birth control while taking XELODA

What are the most common side effects of XELODA?

The most common side effects of XELODA are:

- diarrhea, nausea, vomiting, sores in the mouth and throat (stomatitis), stomach area pain (abdominal pain), upset stomach, constipation, loss of appetite, and too much water loss from the body (dehydration). These side effects are more common in patients age 80 and older.
- hand-and-foot syndrome (palms of the hands or soles of the feet tingle, become numb, painful, swollen or red), rash, dry, itchy or discolored skin, nail problems, and hair loss
- tiredness, weakness, dizziness, headache, fever, pain (including chest, back, joint, and muscle pain), trouble sleeping, and taste problems

These side effects may differ when taking XELODA with docetaxel (TAXOTERE). Please consult your doctor for possible side effects that may be caused by taking XELODA with docetaxel (TAXOTERE).

If you are concerned about these or any other side effects while taking XELODA, talk to your doctor.

Stop taking XELODA immediately and contact your doctor right away if you have the side effects listed below, or other side effects that concern you. Your doctor can then adjust XELODA to a dose that is right for you or stop your XELODA treatment for a while. This should help to reduce the side effects and stop them from getting worse.

- **Diarrhea:** if you have an additional 4 bowel movements each day beyond what is normal or any diarrhea at night
- **Vomiting:** if you vomit more than once in a 24-hour time period
- **Nausea:** if you lose your appetite, and the amount of food you eat each day is much less than usual
- **Stomatitis:** if you have pain, redness, swelling or sores in your mouth
- **Hand-and-Foot Syndrome:** if you have pain, swelling or redness of your hands or feet that prevents normal activity
- **Fever or Infection:** if you have a temperature of 100.5°F or greater, or other signs of infection

Your doctor may tell you to lower the dose or to 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 your side effects have improved, your doctor will tell you whether to start taking XELODA again and what dose to take. Adjusting the dose of XELODA to be right for each patient is an important part of treatment.

How should I store and use XELODA?

- Never share XELODA with anyone
- Store XELODA at normal room temperature (about 65° to 85°F)
- Keep XELODA and all other medicines out of the reach of children
- If you take too much XELODA by mistake, contact your doctor or local poison control center or emergency room **right away**

General advice about prescription medicines:

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use XELODA for a condition for which it was not prescribed. Do not give XELODA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about XELODA. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about XELODA that is written for health professionals.

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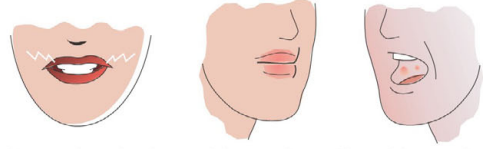

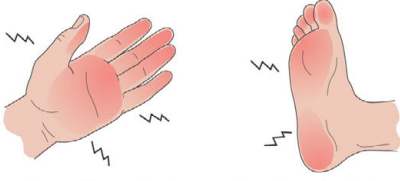

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Important Side Effect Information		STOP taking XELODA immediately and contact your doctor if any of these symptoms occur.	
XELODA[®] (capecitabine) Tablets			
 Moderate diarrhea. (increase of 4-6 stools a day)	 Diarrhea at night.	 Moderate pain and redness of the mouth, swelling of the mouth or mouth sores.	
 Nausea and vomiting.	 Moderate pain, swelling and redness of hands and/or feet.		 If you have a temperature of 100.5°F or greater, or other signs of infection.
<ul style="list-style-type: none">• 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 or what dose to use.			