

## Patient Information

### XELODA<sup>®</sup> (capecitabine) Tablets

Read this leaflet before you start taking XELODA<sup>®</sup> [zeh-LOE-duh] and each time you renew your prescription. It contains important information. 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 detailed information about your medical condition and this medicine.

#### What is XELODA?

XELODA is a medicine you take by mouth (orally) that is used to treat:

- cancer of the colon or rectum that has spread to other parts of the body (metastatic colorectal cancer) when fluoropyrimidine therapy alone is preferred. Patients and physicians should note that combination chemotherapy has shown a survival benefit compared to 5-FU/LV alone. A survival benefit over 5-FU/LV has not been demonstrated with XELODA monotherapy.
- breast cancer that has spread to other parts of the body and has not responded to treatment with certain other medicines. These medicines include paclitaxel (Taxol<sup>®</sup>) and anthracycline-containing therapy such as Adriamycin<sup>®</sup> and doxorubicin.

XELODA is changed in the body to the substance 5-fluorouracil. In some patients with colon, rectum or breast cancer, this substance stops cancer cells from growing and decreases the size of the tumor.

#### 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.

##### 2. TELL YOUR DOCTOR IF YOU

- **take a blood thinner such as warfarin (Coumadin<sup>®</sup>). 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 how fast your blood clots more frequently and adjust the dose of the blood thinner, if needed.**
- take phenytoin (Dilantin<sup>®</sup>). Your doctor needs to test the levels of phenytoin in your blood more often or change your dose of phenytoin.

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- are pregnant. XELODA may not be right for you.
- have kidney problems. Your doctor may prescribe a different medicine or reduce the XELODA dose.
- have liver problems. You may need to be checked for liver problems while you take XELODA.
- take the vitamin folic acid. It may affect how XELODA works.

### **How should I take XELODA?**

Your doctor will prescribe a dose and treatment plan that is right for *you*. Your doctor may want you to take a combination of 150 mg and 500 mg tablets for each dose. If a combination of tablets is prescribed, you must correctly 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 and have 150 engraved on one side. The 500 mg tablets are peach in color and have 500 engraved on one side. Your doctor may change the amount of medicine you take during your treatment. Your doctor may prescribe XELODA Tablets in combination with Taxotere<sup>®</sup> or docetaxel injection.

- Take the tablets in the combination prescribed by your doctor for your **morning and evening** doses.
- Take the tablets **within 30 minutes after the end of a meal** (breakfast and dinner).
- **Swallow XELODA with water.**
- If you miss a dose of XELODA, do not take the missed dose at all and do not double the next one. Instead, continue your regular dosing schedule and check with your doctor.
- It is recommended that XELODA be taken for 14 days followed by a 7-day rest period (no drug), given as a 21-day cycle. Your doctor will tell you how many cycles of treatment you will need.
- In case of accidental swallowing, or if you suspect that too much medicine has been taken, 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.
- Men should practice birth control measures while taking XELODA.
- Do not breast-feed. XELODA may pass through your milk and harm the baby.

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### **What are the most common side effects of XELODA?**

The most common side effects of XELODA are:

- diarrhea, nausea, vomiting, stomatitis (sores in mouth and throat), abdominal (stomach area) pain, upset stomach, constipation, loss of appetite, and dehydration (too much water loss from the body). 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 in combination with Taxotere. Please consult your doctor for possible side effects that may be caused by taking XELODA with Taxotere.

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

**Contact your doctor right away** if you have the side effects listed below. Your doctor can help reduce the chance that the side effects will continue or become serious. Your doctor may tell you to decrease the dose or stop XELODA treatment for a while.

#### **Contact your doctor right away if you have:**

- **Diarrhea:** if you have more than 4 bowel movements each day 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 and 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

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 dose to use.

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### **How should I store and use XELODA?**

- **Never share XELODA with anyone.**
- **XELODA should be stored at normal room temperature (about 65° to 85° F).**
- **Keep this and all other medications out of the reach of children.**
- **In case of accidental ingestion or if you suspect that more than the prescribed dose of this medication has been taken, contact your doctor or local poison control center or emergency room IMMEDIATELY.**

### **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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