Patient Information
XELODA® (zeh-LOE-duh)
(capecitabine)
tablets

What is the most important information I should know about XELODA?

XELODA can cause serious side effects, including:

- **Increased risk of bleeding when taking XELODA with blood thinner medicines, such as warfarin**. **Taking XELODA with these medicines can cause changes in how fast your blood clots and can cause bleeding that can lead to death**. This can happen as soon as a few days after you start taking XELODA, or later during treatment, and possibly within 1 month after you stop taking XELODA. This can happen in people whose cancer has spread to the liver (liver metastasis) **and** in people whose cancer has not spread to the liver.
  - Before taking XELODA, tell your healthcare provider if you are taking warfarin or another blood thinner medicine.
  - If you take warfarin or another blood thinner that is like warfarin during treatment with XELODA, your healthcare provider should do blood tests more often, to check how fast your blood clots during and after you stop treatment with XELODA. Your healthcare provider may change your dose of the blood thinner medicine if needed.
  - **Tell your healthcare provider right away if you develop any signs or symptoms of bleeding.**

See **"What are the possible side effects of XELODA?"** for more information about side effects.

What is XELODA?

XELODA is a prescription medicine used to treat:

- A kind of cancer called colon or rectal (colorectal) cancer. XELODA may be used:
  - alone or in combination with other chemotherapy medicines in people with colon cancer that has spread to lymph nodes in the area close to the colon (Stage III colon cancer), to help prevent your cancer from coming back after you have had surgery.
  - adults with rectal cancer, around the time of your surgery, as a part of chemotherapy and radiation (chemoradiation) treatment when your rectal cancer has spread to nearby tissues (locally advanced).
  - alone or in combination with other chemotherapy medicines, when your colorectal cancer cannot be removed by surgery or has spread to other areas of your body (metastatic).
- A kind of cancer called breast cancer. XELODA may be used in people with breast cancer that is advanced or has spread to other parts of the body (metastatic):
  - alone if you are not able to receive an anthracycline medicine or taxane-containing chemotherapy.
  - in combination with docetaxel when you have received anthracycline containing chemotherapy and it is no longer working.
- Kinds of cancer called stomach (gastric), esophageal, or gastroesophageal junction (GEJ) cancer. XELODA may be used in adults:
  - in combination with other chemotherapy medicines when your cancer of the stomach, esophagus, or GEJ cannot be removed by surgery or has spread to other parts of the body (metastatic).
  - when your cancer of the stomach, esophagus, or GEJ is metastatic adenocarcinoma, **and:**
    - is HER2-positive, **and**
    - you have not received treatment with XELODA in combination with other treatments for your metastatic cancer.
- A kind of cancer called pancreatic cancer. XELODA may be used to treat adults in combination with other chemotherapy medicines, to help prevent your pancreatic cancer from coming back after you have had surgery.

It is not known if XELODA is safe and effective in children.

Do not take XELODA if you:

- have had a severe allergic reaction to fluorouracil or capecitabine. See the end of this leaflet for a complete list of ingredients in XELODA.

Talk to your healthcare provider before taking XELODA if you are not sure.

Before taking XELODA, tell your healthcare provider about all your medical conditions, including if you:
See **"What is the most important information I should know about XELODA?"**

- have had heart problems.
- have kidney or liver problems.
- are pregnant or plan to become pregnant. XELODA can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with XELODA.
- Use an effective method of birth control (contraception) during treatment and for 6 months after your last dose of XELODA. Talk to your healthcare provider about birth control choices that may be right for you during treatment with XELODA.
- Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with XELODA.

Males who have female partners who are able to become pregnant should use effective birth control during treatment and for 3 months after your last dose of XELODA.

- are breastfeeding or plan to breastfeed. It is not known if XELODA passes into your breast milk. Do not breastfeed during treatment with XELODA and for 1 week after your last dose of XELODA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. XELODA may affect the way other medicines work, and other medicines may affect the way XELODA works.

How should I take XELODA?

- Take XELODA exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much XELODA to take and when to take it. The number of days that you will take XELODA during each treatment cycle and the number of days in each treatment cycle depends on the type of cancer you are being treated for.
- Take XELODA 2 times a day at the same time each day, about 12 hours apart.
- Take XELODA within 30 minutes after finishing a meal.
- Swallow XELODA tablets whole with water. **Do not** chew, cut, or crush XELODA tablets. See "Eye irritation, skin rash and other side effects with exposure to crushed XELODA tablets" in the section called "**What are the possible side effects of XELODA?**"
- If you cannot swallow XELODA tablets whole, tell your healthcare provider.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with XELODA if you develop side effects.
- **Do not** take products that contain folic acid or folate analog products, for example, leucovorin or levoleucovorin, during treatment with XELODA, unless your healthcare provider instructs you to take it.
- If you vomit after taking a dose of XELODA, do not take another dose at that time. Wait and take your next dose of XELODA at your scheduled time.
- If you miss a dose of XELODA, just skip the dose and then take your next dose at your scheduled time.
- If you take too much XELODA, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of XELODA?

XELODA can cause serious side effects including:

- See **"What is the most important information I should know about XELODA?"**
- **Serious side effects in people with dihydropyrimidine dehydrogenase (DPD) enzyme deficiency.** People with certain changes in a gene called "DPYD" may have a deficiency of the DPD enzyme. Some of these people may not produce enough DPD enzyme, and some of these people may not produce the DPD enzyme at all.
  - People who do not produce any DPD enzyme are at increased risk of sudden side effects that come on early during treatment with XELODA and can be serious, and sometimes lead to death. **Call your healthcare provider right away if you develop any of the following symptoms and they are severe**, including:
    - sores of the mouth, tongue, throat and esophagus (mucositis)
    - diarrhea
    - low white blood cell counts
    - nervous system problems.
  - People with some DPD enzyme may have an increased risk of serious side effects with XELODA treatment that can sometimes lead to death.

  Your healthcare provider should talk with you about DPYD testing to look for DPD deficiency.
- **Heart problems.** XELODA can cause heart problems including: heart attack and decreased blood flow to the heart, chest pain, irregular heartbeats, changes in the electrical activity of your heart seen on an electrocardiogram (ECG), problems with your heart muscle, heart failure, and sudden death. You may have an increased risk of heart problems with XELODA if you have a history of narrowing or blockage of the coronary arteries (coronary artery disease). **Stop taking XELODA and call your healthcare provider or go to the nearest hospital emergency room right away if you get any new symptoms of a heart problem including:**
  - chest pain
  - shortness of breath
  - dizziness
  - lightheadedness

- **Diarrhea.** Diarrhea is common with XELODA and can sometimes be severe. Stop taking XELODA and call your healthcare provider right away if the number of bowel movements you have in a day increases by 4 or more bowel movements than what is usual for you, or if you have bowel movements at night. Ask your healthcare provider about what medicines you can take to treat your diarrhea. Stop taking XELODA if you have severe bloody diarrhea with severe abdominal pain and fever and call you healthcare provider right away.
- **Loss of too much body fluid (dehydration) and kidney failure.** Dehydration can happen with XELODA and may affect how well your kidneys work. If you take XELODA with certain other medicines that can cause kidney problems, you may have an increased risk of serious kidney failure that can sometimes lead to death. Your risk of kidney failure may also be increased if you have kidney problems before taking XELODA.

  Nausea, and vomiting are common with XELODA. If you lose your appetite, feel weak, and have nausea, vomiting, or diarrhea, you can quickly become dehydrated.

  Stop taking XELODA and call your healthcare provider right away if you:
  - vomit 2 or more times in a day.
  - are only able to eat or drink a little now and then, or not at all due to nausea.
  - have diarrhea. See "diarrhea" above.

  You may need to receive fluids through your vein (intravenous) to treat your dehydration or receive treatment for kidney failure.
- **Severe skin and mouth reactions.**
  - XELODA can cause severe skin reactions that may lead to death. Tell your healthcare provider right away if you develop a skin rash, blister and peeling of your skin. Your healthcare provider may tell you to stop taking XELODA if you have a serious skin reaction. Do not take XELODA again if this happens.
  - XELODA can also cause "hand and foot" syndrome. Hand and foot syndrome is common with XELODA and can cause you to have numbness and changes in sensation in your hands and feet, or cause redness, pain, swelling of your hands and feet. Stop taking XELODA and call your healthcare provider right away if you have any of these symptoms and you are not able to do your usual activities.
  - Hand and foot syndrome can lead to a loss of fingerprints which could impact your identification.
  - You may get sores in your mouth or on your tongue when taking XELODA. Stop taking XELODA and call your healthcare provider right away if you get painful redness, swelling, or ulcers in your mouth or tongue, or if you are having problems eating.
- **Decreased white blood cells, platelets, and red blood cell counts. Decreased white blood cells, platelets, and red blood cell counts can happen with XELODA and can sometimes be severe.** Your healthcare provider will do blood tests during treatment with XELODA to check your blood cell counts.

  If your white blood cell count is very low, you are at increased risk for infection. Call your healthcare provider right away if you develop a fever of 100.5ºF or greater or have other signs and symptoms of infection.
- **Increased level of bilirubin in your blood and liver problems.** Increased bilirubin in your blood is common with XELODA and can also sometimes be severe. Your healthcare provider will check you for these problems during treatment with XELODA. Tell your healthcare provider right away if you develop yellowing of your skin or the white part of your eyes.
- **Eye irritation, skin rash and other side effects with exposure to crushed XELODA tablets.** If you come into contact with (you are exposed to) crushed XELODA tablets, you may develop side effects including:
  - eye irritation and swelling
  - skin rash
  - diarrhea
  - feeling like pins and needles in your hands
  - headache
  - stomach irritation
  - nausea and vomiting

  Do not chew, cut, or crush XELODA tablets. See **"How should I take XELODA tablets**."

  If for any reason your tablets must be cut or crushed, this must be done by your pharmacist or healthcare provider.

Your healthcare provider may decide to decrease your dose, or temporarily or permanently stop XELODA if you have serious side effects with XELODA.

The most common side effects in people with colon cancer who take XELODA alone to help prevent it from coming back include: hand and foot syndrome, diarrhea, and nausea.

The most common side effects in people with metastatic colorectal carcinoma who take XELODA alone include:

- decreased red blood cell count

- diarrhea
- hand and foot syndrome
- increased bilirubin level in your blood
- nausea
- tiredness
- stomach-area (abdominal) pain

The most common side effects in people with metastatic breast cancer who take XELODA in combination with docetaxel include:

- diarrhea
- mouth sores or mouth inflammation
- hand and foot syndrome
- nausea and vomiting
- hair loss
- swelling
- stomach-area (abdominal) pain

The most common side effects in people with metastatic breast cancer who take XELODA alone include:

- decreased white blood cell and red blood cell count
- diarrhea
- hand and foot syndrome
- nausea and vomiting
- tiredness
- skin inflammation, including rash

Severe allergic reactions can happen with XELODA. See "**Do not take XELODA if you**:" **Stop taking XELODA and call your healthcare provider right away or go to an emergency room if you have any of the following symptoms of a severe allergic reaction to XELODA:**

- red itchy welts on your skin (hives)
- rash
- skin redness
- itching
- swelling of your face, lips, tongue or throat
- trouble swallowing or breathing

XELODA may cause fertility problems in females and males. This may affect the ability to have a child. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of XELODA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store XELODA?

- Store XELODA at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep XELODA in a tightly closed container.
- Ask your healthcare provider or pharmacist how to safely throw away any unused XELODA.

Keep XELODA and all medicines out of the reach of children.

General information about the safe and effective use of XELODA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. 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. You can ask your pharmacist or healthcare provider for information about XELODA that is written for health professionals.

What are the ingredients in XELODA?

Active ingredient: capecitabine

Inactive ingredients: anhydrous lactose, croscarmellose sodium, hydroxypropyl methylcellulose, microcrystalline cellulose, magnesium stearate and purified water. The peach or light peach film coating contains hydroxypropyl methylcellulose, talc, titanium dioxide, and synthetic yellow and red iron oxides.

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For more information, go to http://www.gene.com/patients/medicines/xeloda or call 1-877-436-3683.

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