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Capecitabine: Patient drug information

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(For additional information see "Capecitabine: Drug information")

Brand Names: US Xeloda

Brand Names: Canada Teva-Capecitabine; Xeloda

Warning

· Very bad and sometimes deadly bleeding problems have happened in people taking this drug with some blood thinners like warfarin. This has happened within a few days after this drug was started and up to 1 month after this drug was stopped. Your risk for bleeding problems is higher if you are older than 60 or have cancer. If you are taking a blood thinner, talk with your doctor. You may need to have your blood work checked often. Talk with your doctor.

What is this drug used for?

- It is used to treat colorectal cancer.
- It is used to treat breast cancer.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to capecitabine, fluorouracil (5-FU), or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- If you have a dihydropyrimidine dehydrogenase (DPD) deficiency or kidney disease.
- · If you are breast-feeding. Do not breast-feed while you take this drug and for 2 weeks after your last dose.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- It is common to have loose stools (diarrhea) when taking this drug. Some cases of loose stools may
 cause fluid loss and kidney problems that can sometimes be deadly. Call your doctor right away if you
 have loose stools that do not go away or if you have very loose stools. Do not try to treat loose stools
 without first checking with your doctor.
- Dehydration has happened in people taking this drug. Dehydration may cause very bad kidney
 problems that can be deadly. The chance may be higher in people who already have kidney problems
 or who are taking drugs that can cause kidney problems. The chance may also be raised in people
 who have loss of appetite, upset stomach, throwing up, loose stools (diarrhea), or weakness. Talk with
 the doctor.
- The chance of very bad and sometimes deadly side effects is raised in patients who do not have the enzyme dihydropyrimidine dehydrogenase (DPD) in the body. These include mouth irritation or sores, loose stools (diarrhea), low white blood cell counts, or nerve problems. Talk with the doctor.
- Heart problems like heart attack, heart failure, and a heartbeat that does not feel normal have happened with this drug. Sudden deaths have also happened. These effects may be more common in people who have ever had heart disease before. Talk with your doctor.
- A very bad skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause very bad health problems that may not go away, and sometimes death. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in your mouth, throat, nose, or eyes.
- A problem called hand and foot syndrome can happen. If it is bad or lasts for a long time, this can lead to loss of fingerprints. Talk with the doctor.
- If you are over the age of 60, use this drug with care. You could have more side effects.
- This drug may affect fertility. Fertility problems may lead to not being able to get pregnant or father a child. Talk with the doctor.
- If you are a man and have sex with a female who could get pregnant, protect her from pregnancy during care and for 3 months after care ends. Use birth control that you can trust.
- If you are a man and your sex partner gets pregnant while you take this drug or within 3 months after your last dose, call your doctor right away.
- This drug may cause harm to the unborn baby if you take it while you are pregnant.
- If you are able to get pregnant, a pregnancy test will be done to show that you are NOT pregnant before starting this drug. Talk with your doctor.
- Use birth control that you can trust to prevent pregnancy while taking this drug and for 6 months after stopping this drug.
- If you get pregnant while taking this drug or within 6 months after your last dose, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

• Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or

without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of bleeding like throwing up blood or throw up that looks like coffee grounds; coughing up blood; blood in the urine; black, red, or tarry stools; bleeding from the gums; vaginal bleeding that is not normal; bruises without a reason or that get bigger; or any bleeding that is very bad or that you cannot stop.
- Signs of fluid and electrolyte problems like mood changes, confusion, muscle pain or weakness, a
 heartbeat that does not feel normal, very bad dizziness or passing out, fast heartbeat, more thirst,
 seizures, feeling very tired or weak, not hungry, unable to pass urine or change in the amount of urine
 produced, dry mouth, dry eyes, or very bad upset stomach or throwing up.
- Signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Shortness of breath, a big weight gain, or swelling in the arms or legs.
- Chest pain or pressure.
- A heartbeat that does not feel normal.
- · Numbness or tingling in the hands or feet.
- Mouth irritation or mouth sores.
- Very bad belly pain.
- Change in eyesight, eye pain, or very bad eye irritation.
- Redness or irritation of the palms of hands or soles of feet.
- Swollen gland.
- Mood changes.
- Swelling, warmth, numbness, change of color, or pain in a leg or arm.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- · Headache.
- Dizziness.
- Not able to sleep.
- · Change in nails.
- Upset stomach or throwing up.
- Not hungry.
- · Loose stools (diarrhea).
- Hard stools (constipation).
- · Feeling tired or weak.
- · Belly pain.
- Eye irritation.
- Dry skin.

- Back pain.
- Muscle or joint pain.
- · Hair loss.
- Change in taste.
- Weight loss.
- Bone pain.
- Flushing.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take after a meal, within 30 minutes.
- Swallow whole with a full glass of water.
- If the tablets must be cut or crushed, do not do it by yourself. Talk with the doctor.
- To gain the most benefit, do not miss doses.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- If you have upset stomach, throwing up, loose stools (diarrhea), or are not hungry, talk with your doctor. There may be ways to lower these side effects.
- Talk with your doctor before getting any vaccines. Use with this drug may either raise the chance of an infection or make the vaccine not work as well.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- This drug may affect how much of some other drugs are in your body. If you are taking other drugs, talk with your doctor. You may need to have your blood work checked more closely while taking this drug with your other drugs.

What do I do if I miss a dose?

- Skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

• Store at room temperature.

- Store in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Check with your pharmacist about how to throw out unused drugs.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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