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Patient Information

Capecitabine (KAP e SYE ta been) Tablets, USP

What is the most important information I should know about capecitabine tablets?

Capecitabine tablets can cause serious side effects, including:

- **Increased risk of bleeding when taking capecitabine tablets with blood thinner medicines, such as warfarin. Taking capecitabine tablets 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 capecitabine tablets, or later during treatment, and possibly within 1 month after you stop taking capecitabine tablets. 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 capecitabine tablets, 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 capecitabine tablets, your healthcare provider should do blood tests more often, to check how fast your blood clots during and after you stop treatment with capecitabine tablets. 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 capecitabine tablets?**” for more information about side effects.

What are capecitabine tablets?

Capecitabine tablets are prescription medicine used to treat:

- A kind of cancer called colon or rectal (colorectal) cancer. Capecitabine tablets 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. capecitabine tablets 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. Capecitabine tablets 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 capecitabine tablets in combination with other treatments for your metastatic cancer.
- A kind of cancer called pancreatic cancer. Capecitabine tablets 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 capecitabine tablets are safe and effective in children.

Do not take capecitabine tablets 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 capecitabine tablets.

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

Before taking capecitabine tablets, tell your healthcare provider about all your medical conditions, including if you:

See “**What is the most important information I should know about capecitabine tablets?**”

- have had heart problems.
- have kidney or liver problems.
- are pregnant or plan to become pregnant. Capecitabine tablets 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 capecitabine tablets.
 - Use an effective method of birth control (contraception) during treatment and for 6 months after your last dose of capecitabine tablets. Talk to your healthcare provider about birth control choices that may be right for you during treatment with capecitabine tablets.

- Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with capecitabine tablets.

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 capecitabine tablets.

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

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

How should I take capecitabine tablets?

- Take capecitabine tablets exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how many capecitabine tablets to take and when to take it. The number of days that you will take capecitabine tablets 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 capecitabine tablets 2 times a day at the same time each day, about 12 hours apart.
- Take capecitabine tablets within 30 minutes after finishing a meal.
- Swallow capecitabine tablets whole with water. **Do not** chew, cut, or crush capecitabine tablets. See “Eye irritation, skin rash and other side effects with exposure to crushed capecitabine tablets” in the section called “**What are the possible side effects of capecitabine tablets?**”
- If you cannot swallow capecitabine tablets whole, tell your healthcare provider.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with capecitabine tablets 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 capecitabine tablets, unless your healthcare provider instructs you to take it.
- If you vomit after taking a dose of capecitabine tablets, do not take another dose at that time. Wait and take your next dose of capecitabine tablets at your scheduled time.
- If you miss a dose of capecitabine tablets, just skip the dose and then take your next dose at your scheduled time.
- If you take too many capecitabine tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of capecitabine tablets? Capecitabine tablets can cause serious side effects including:

- See “**What is the most important information I should know about capecitabine tablets?**”
- **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 capecitabine tablets 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 capecitabine tablets treatment that can sometimes lead to death.

Your healthcare provider should talk with you about DPYD testing to look for DPD deficiency.

- **Heart problems.** Capecitabine tablets 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 capecitabine tablets if you have a history of narrowing or blockage of the coronary arteries (coronary artery disease). **Stop taking capecitabine tablets 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
 - dizziness
 - shortness of breath
 - lightheadedness
- **Diarrhea.** Diarrhea is common with capecitabine tablets and can sometimes be severe. Stop taking capecitabine tablets 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 capecitabine tablets 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 capecitabine tablets and may affect how well your kidneys work. If you take capecitabine tablets 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 capecitabine tablets. Nausea, and vomiting are common with capecitabine tablets. If you lose your appetite, feel weak, and have nausea, vomiting, or diarrhea, you can quickly become dehydrated.

Stop taking capecitabine tablets 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.**

- Capecitabine tablets 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 capecitabine tablets if you have a serious skin reaction. Do not take capecitabine tablets again if this happens.
- Capecitabine tablets can also cause “hand and foot” syndrome. Hand and foot syndrome is common with capecitabine tablets 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 capecitabine tablets 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 capecitabine tablets. Stop taking capecitabine tablets 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 capecitabine tablets and can sometimes be severe.** Your healthcare provider will do blood tests during treatment with capecitabine tablets 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 100.5°F 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 capecitabine tablets and can also sometimes be severe. Your healthcare provider will check you for these problems during treatment with capecitabine tablets. 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 capecitabine tablets.** If you come into contact with (you are exposed to) crushed capecitabine tablets, you may develop side effects including:
 - eye irritation and swelling
 - feeling like pins and needles in your hands
 - skin rash
 - headache
 - diarrhea
 - stomach irritation
 - nausea and vomiting

Do not chew, cut, or crush capecitabine tablets. See “How should I take capecitabine 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 capecitabine tablets if you have serious side effects with capecitabine tablets.

The most common side effects in people with colon cancer who take capecitabine tablets 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 capecitabine tablets alone include:

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

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

- diarrhea
- hair loss
- mouth sores or mouth inflammation
- swelling

- hand and foot syndrome
- stomach-area (abdominal) pain
- nausea and vomiting

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

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

Severe allergic reactions can happen with capecitabine tablets. See “Do not take capecitabine tablets if you:” **Stop taking capecitabine tablets 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 capecitabine tablets:**

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

Capecitabine tablets 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 capecitabine tablets.

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 capecitabine tablets?

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

Keep capecitabine tablets and all medicines out of the reach of children.

General information about the safe and effective use of capecitabine tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use capecitabine tablets for a condition for which it was not prescribed. Do not give capecitabine tablets 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 capecitabine tablets that is written for health professionals.

What are the ingredients in capecitabine tablets?

Active ingredient: capecitabine

Inactive ingredients: microcrystalline cellulose, croscarmellose sodium, hypromellose, anhydrous lactose, talc and magnesium stearate. The peach or light peach film coating contains hypromellose, titanium dioxide, lactose monohydrate, polyethylene glycol, red iron oxide and yellow iron oxide.

For more information, call 1-800-818-4555.

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