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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:

- Capecitabine tablets can interact with blood thinner medicines, such as warfarin (COUMADIN®). 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 even within 1 month after you stop taking capecitabine tablets. Your risk may be higher because you have cancer, and if you are over 60 years of age.
- Before taking capecitabine tablets, tell your healthcare provider if you are taking warfarin (COUMADIN®) or another blood thinner medicine.
- If you take warfarin (COUMADIN®) or another blood thinner that is like warfarin (COUMADIN®) during treatment with capecitabine tablets, your healthcare provider should do blood tests 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.

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 people with:

- cancer of the colon that has spread to lymph nodes in the area close to the colon (Dukes' C stage), after they have surgery.
 - cancer of the colon or rectum (colorectal) that has spread to other parts of the body (metastatic).
 - breast cancer that has spread to other parts of the body (metastatic) together with another medicine called docetaxel after treatment with certain other anti-cancer medicines have not worked.
 - breast cancer that has spread to other parts of the body and has not improved after treatment with paclitaxel and certain other anti-cancer medicines, or who cannot receive any more treatment with certain anti-cancer medicines.
- It is not known if capecitabine tablet is safe and effective in children.

Do not take capecitabine tablet if you:

- have severe kidney problems.
 - are allergic to capecitabine, 5-fluorouracil, or any of the ingredients in capecitabine tablets. 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 if you have any of the conditions listed above.

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.
- have been told that you lack the enzyme DPD (dihydropyrimidine dehydrogenase).
- are pregnant or plan to become pregnant. Capecitabine tablets can harm your unborn baby. Your healthcare provider should do a pregnancy test before you start 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.
 - o **Females** who are able to become pregnant should use effective birth control during treatment and for 6 months after the final dose. Talk to your healthcare provider about birth control choices that may be right for you during treatment with capecitabine tablets.
 - o **Males** who have female partners who are able to become pregnant should use effective birth control during treatment and for 3 months after the final dose.

- 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 2 weeks after the final dose. 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 tablet works. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

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 much capecitabine tablets to take and when to take it.
- Take capecitabine tablets 2 times a day, 1 time in the morning and 1 time in the evening.
- Take capecitabine tablets within 30 minutes after finishing a meal.
- Swallow capecitabine tablets whole with water. Do not crush or cut 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.
- If you take too much 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 may cause serious side effects including:

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

- **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 than is usual for you. Ask your healthcare provider about what medicines you can take to treat your diarrhea. If you have severe bloody diarrhea with severe abdominal pain and fever, call your healthcare provider or go to the nearest hospital emergency room right away.
- **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. Stop taking capecitabine tablets and call your healthcare provider right away if you get any of the following symptoms:
 - o chest pain
 - o shortness of breath
 - o feeling faint
 - o irregular heartbeats or skipping beats
 - o sudden weight gain
 - o swollen ankles or legs
- **Loss of too much body fluid (dehydration) and kidney failure.** Dehydration can happen with capecitabine tablets and may cause sudden kidney failure that can lead to death. You are at higher risk if you have kidney problems before taking capecitabine tablets and also take other medicines that can cause kidney problems. 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 doctor 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.
- **Serious skin and mouth reactions.**
 - Capecitabine tablets can cause serious skin reactions that may lead to death. Tell your healthcare provider right away if you develop a skin rash, blisters 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.

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Size: 365x235 mm



Capecitabine Tablets USP

Artwork Type: **PATIENT INFORMATION LEAFLET**

Artwork Code: **PJPI0407A**

Void Code: **PJPI0407**

Dimension: **365x235 mm**

Void A/W Reason:

Country: **ANDA-US**

Language: **ENGLISH**

Mfg. Location: **HALOL**

Specification/Type of Paper:

Super Fine 41 GSM ITC Paper

Folding: **30 pages pad**

365--2--91.25 mm

235--0--235 mm

Glueing on 235 mm side

Special Req.:

Remark (if any):

Prepared by: **SAPNA**

Checked by:

Approved by:

Approved by RA:

APPROVAL HISTORY ATTACHED

No. of Colors: 1

Black

- 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 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 if you get painful redness, swelling, or ulcers in your mouth and tongue, or if you are having problems eating.
- **Increased level of bilirubin in your blood and liver problems.** Increased bilirubin in your blood is common with capecitabine tablets. Your healthcare provider will check you for these problems during treatment with capecitabine tablets.
- **Decreased white blood cells, platelets, and red blood cell counts.** 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.
People 80 years of age or older may be more likely to develop severe or serious side effects with capecitabine tablets.

The most common side effects of capecitabine tablets include:

- diarrhea
- hand and foot syndrome
- nausea
- vomiting
- stomach-area (abdominal) pain
- tiredness
- weakness
- increased amounts of red blood cell breakdown products (bilirubin) in your blood

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.

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.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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Distributed by:

Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512



Manufactured by:
Sun Pharmaceutical Industries Limited
Halol-Baroda Highway,
Halol-389 350, Gujarat, India.

PJPI0407A
ISS: 09/2019

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