



**GENERIC NAME:** capecitabine

#### **DRUG CLASS AND MECHANISM**

Capecitabine is an oral medication for treating advanced breast cancers that are resistant to combination therapy with the drugs of choice, paclitaxel (Taxol) and a drug from the anthracycline family of drugs, for example, doxorubicin (Adriamycin). Capecitabine is converted by the body to 5-fluorouracil (5-FU), a drug which has been given intravenously for many years to treat various types of cancer. It is not surprising, therefore, that capecitabine also is effective in the treatment of colorectal cancer, a type of cancer which is treated frequently with 5-FU. 5-FU inhibits the production of both DNA and protein by the cancerous cells that are necessary for the cells to divide and the cancer to grow in size. Capecitabine was approved by the FDA in 1998 for the treatment of breast cancer and in 2005 for the treatment of colorectal cancer.

PRESCRIPTION: Yes

PREPARATIONS: Tablets: 150 and 500 mg.

#### PRESCRIBED FOR

Capecitabine is used for treating women with breast cancer that is resistant to other more commonly-used drugs. It also is used following surgery for colorectal cancer if the cancer has spread to lymph nodes (Dukes' C stage).

#### **DRUG INTERACTIONS**

Tell your doctor of all prescription and nonprescription drugs you use, especially of: leucovorin, "blood thinners" (e.g., warfarin), folic acid, vitamins containing folic acid, other anti-cancer drugs, phenytoin, fosphenytoin. Do not start or stop any medicine without doctor or pharmacist approval.

#### USES

Capecitabine is used to treat cancer (e.g., breast or colorectal). Capecitabine kills cancer cells and shrinks tumors by blocking the process by which the cells divide and are formed (DNA/RNA synthesis).

## **HOW TO USE**

Take this medication by mouth usually twice daily with food as directed by your doctor. It is best taken at the end of a meal with a full glass of water. Capecitabine is taken every day for 2 weeks followed by one week without taking this medication. This course of treatment may then be repeated as directed by your doctor. The dosage is based on your medical condition and response to therapy. Your dosage may need to be adjusted using a different number of tablets and tablet strengths. Pay close attention to your dosage.

## SIDE EFFECTS

Nausea, vomiting, diarrhea, loss of appetite, constipation, weakness, body aches, headache, dizziness, trouble sleeping, or dry, red, itchy skin may occur. If these effects persist or worsen, notify your doctor. Stop taking capecitabine and tell your doctor immediately if you have any of these serious side effects: severe vomiting (2 or more times per day), severe diarrhea (4 or more times per day), persistent sore throat or fever, unusual bruising or bleeding, pain/swelling/redness or numbness of the hands and feet, sores in mouth. Tell your doctor immediately if you have any of these unlikely but serious side effects: yellowing of the eyes or skin, dark urine, stomach pain, chest pain, trouble breathing. If you notice other side effects not listed above, contact your doctor or pharmacist.

## DOSING

Capecitabine generally is taken twice daily, with the two doses approximately 12 hours apart. Tablets should be taken 30 minutes after eating. Capecitabine usually is prescribed in repeated cycles of 3-weeks, with the drug taken for two consecutive weeks followed by a week without drug. Some patients may need lower or delayed dosing. As always, the physician's dosing instructions should be followed.

## **OVERDOSE**

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include nausea, vomiting,

diarrhea, and stomach irritation and bleeding.

#### MISSED DOSE

If you miss a dose, contact your doctor or pharmacist to establish a new dosing schedule.

#### STORAGE

Store at room temperature at 77 degrees F (25 degrees C) in a tightly closed container. Brief storage between 59 and 86 degrees F (15 - 30 degrees C) is permitted. Keep away from light and moisture.

#### **PRECAUTIONS**

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: severe kidney disease, a certain enzyme deficiency (dihydropyrimidine dehydrogenase deficiency). Before using this medication, tell your doctor or pharmacist your medical history, especially of: heart-related problems, liver problems, blood disorders (e.g., bone marrow suppression), kidney disease, allergies (especially to fluorouracil; 5-FU). This medication can lower your body's ability to fight infection. Avoid touching your eyes or inside your nose without first washing your hands. Do not have immunizations/vaccinations without the consent of your doctor and avoid contact with people who have recently received oral polio vaccine. Use caution with sharp objects like safety razors or nail cutters and avoid activities such as contact sports in order to lower the chances of getting cut, bruised or injured. Caution is advised when this drug is used in the elderly, as they may be more sensitive to the side effects of this medication. This drug is not recommended for use during pregnancy. Consult your doctor before using this drug. It is not known if this drug passes into breast milk. Because of the potential risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

#### WARNING

Capecitabine may interact with "blood thinners" (anticoagulants such as warfarin or phenprocoumon) and cause serious bleeding episodes; rarely, deaths have occurred. This increased bleeding risk (increased INR/PT) in some cases has occurred within one month of stopping capecitabine, as well as during treatment. If you are using warfarin, your laboratory tests (INR) will be closely monitored, and you should immediately report any signs of bleeding or bruising, including black stools.

**Note :** This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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