Taj Pharmaceuticals Ltd.

Capecitabine

CAS No. : 154361-50-9

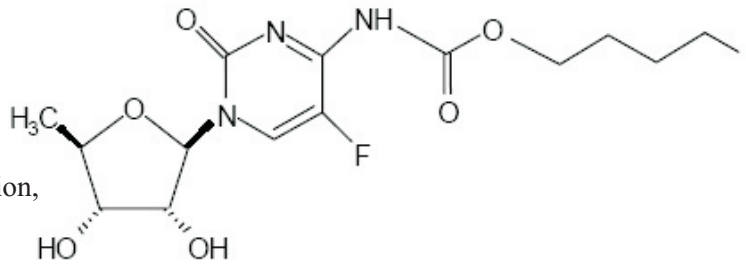
Capecitabine is a chemotherapy drug that is given as a treatment for some types of cancer, including advanced bowel cancer or breast cancer.

Chemical Name:

pentyl[1-(3,4-dihydroxy-5-methyl-tetrahydrofuran-2-yl)- 5-fluoro-2-oxo-1H-pyrimidin- 4-yl]aminomethanoate
Capecitabine Molecular Formula-C15H22FN3O6

Description

CAS number 154361-50-9
Synonym 5'-deoxy-5-fluoro-N-[(pentyloxy) carbonyl]- cytidine, Capecitabine
Molecular Formula C15H22FN3O6
Molecular Weight 359.35
Specifications Available on request
Packing Export worthy packing
Application Chemotherapy drug
Material Safety Data Sheet
Available on request
Availability For your requirements of evaluation, Pilots and Commercial procurement



DOSAGE

Your doctor may want you to take a combination of 500mg and 150mg tablets. You need to make sure that you are taking the right dose.

The tablets should be swallowed whole with a glass of water, within half an hour of the end of a meal, as capecitabine works best if it is broken down in the stomach with food. You should take them in the morning after breakfast, and then again after your evening meal, so that the doses are spaced at least eight hours apart.

If you have trouble swallowing capecitabine tablets, they can be dissolved in a 200ml glass of warm water. The mixture should be stirred with a spoon until the tablets are completely dissolved and drunk immediately. The glass and spoon should be washed and kept separate from your other crockery and cooking utensils.

Capecitabine tablets are usually taken for a number of days, followed by a rest period in which no tablets are taken. This can vary depending upon the type of cancer you have. It is important to follow the instructions carefully and take the tablets as directed by your doctor, nurse or pharmacist.

You should only get the tablets from your hospital. You can't get a repeat prescription from your GP.

* For mild renal dysfunction (creatinine clearance 30-50 mL/min), it is recommended to reduce dose by 25%.
* For severe renal dysfunction (creatinine clearance <30 mL/min), treatment is not recommended.
* There is no recommendation for hepatic dysfunction.
* For elderly patients, lower doses may be required due to higher incidences of serious adverse reactions.

Taj Pharmaceuticals Ltd.
Capecitabine
CAS NO- 154361-50-9

SIDE EFFECTS

Side effects from capecitabine are common and include:

* diarrhea
* nausea
* vomiting
* stomach pain
* constipation
* weakness
* tiredness
* dizziness
* headache
* sleeplessness
* dry or itching skin
* dehydration

If you experience any of the following symptoms or the one listed in the IMPORTANT WARNING section, call your doctor immediately:

* severe diarrhea (more than four bowel movements each day or diarrhea at night)
* decreased appetite (complete loss of appetite or only able to eat occasionally)
* severe vomiting (more than one time in a 24-hour period)
* tingling, numbness, pain, redness, or swelling of the hands or feet
* sores or pain in the mouth or throat
* fever or infection (a temperature of 100.5 degrees F or greater)
* chills
* sore throat
* chest pain
* rash

PRECAUTIONS

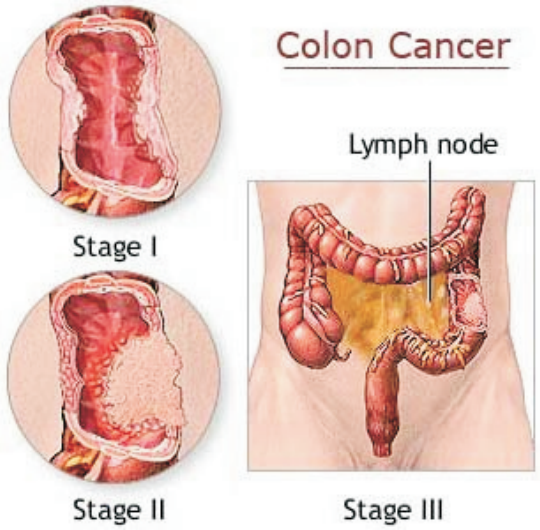
Before taking capecitabine,

* tell your doctor and pharmacist if you are allergic to a capecitabine, fluorouracil, or any other drugs.
* tell your doctor and pharmacist what prescription and nonprescription medications you are taking, especially those listed in the IMPORTANT WARNING section, antacids, folic acid, leucovorin, phenytoin (Dilantin), and vitamins.
* tell your doctor if you have or have ever had heart, liver, or kidney disease.
* women who are pregnant or breast-feeding should tell their doctors before they begin taking this drug. You should not plan to have children while receiving chemotherapy or for a while after treatments. (Talk to your doctor for further details.) Use a reliable method of birth control to prevent pregnancy.
* tell your doctor if you are breast-feeding. Capecitabine can cause serious side effects in nursing infants.
* do not have any vaccinations (e.g., measles or flu shots) without talking to your doctor.

INTERACTIONS

* May interact with warfarin and increase bleeding risk.
* May inhibit cytochrome CYP2C9 enzyme, and therefore increase levels of substrates such as phenytoin and other substrates of CYP2C9.

* Much as fluorouracil, the concomitant use of leucovorin may increase both the efficacy and the toxicity of capecitabine.



DRUG DESCRIPTION

Description:
Name: Capecitabine

Synonyms

Penty [1-(3,4-dihydroxyl-5-methyl-oxolan-2-yl)-5-fluoro-2-oxopyrimidin-4-yl] aminoformate, Xeloda

Molecular Formula: C15H22FN3O6
Molecular Weight: 359.35
CAS: 154361-50-9
Capecitabine is FDA-approved for:

* Adjuvant in colorectal cancer Stage III Dukes' C - used as first-line monotherapy.
* Metastatic colorectal cancer - used as first-line monotherapy, if appropriate.
* Metastatic breast cancer - used in combination with docetaxel, after failure of anthracycline-based treatment. Also as monotherapy, if the patient has failed paclitaxel-based treatment, and if anthracycline-based treatment has either failed or cannot be continued for other reasons (i.e., the patient has already received the maximum lifetime dose of an anthracycline).

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:
http://www.tajapi.com
or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.
This leaflet was prepared by
Taj Pharmaceuticals Limited,
Mumbai (India).
MPSTJ278
Last revised: 29 August 2009