



**Patient information leaflet
(For All Products not subject to Medical Prescription)**

CAPETERO 500 (Capecitabine Tablets USP 500 mg)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Capecitabine tablet is and what it is used for
2. Before you take Capecitabine tablet
3. How to take Capecitabine tablet
4. Possible side effects
5. How to store Capecitabine tablet
6. Further information

1. WHAT CAPECITABINE TABLET IS AND WHAT IT IS USED FOR

CAPECITABINE TABLETS USP 500 MG is a medicine you take by mouth (orally). CAPECITABINE TABLETS USP 500 MG is changed in the body to 5-fluorouracil (5-FU). In some patients with colon, rectum or breast cancer, 5-FU stops cancer cells from growing and decreases the size of the tumor.



CAPECITABINE TABLETS USP 500 MG is used to treat: cancer

of the colon after surgery

cancer of the colon or rectum (colorectal cancer) that has spread to other parts of the body (metastatic colorectal cancer). You should know that in studies, other medicines showed improved survival when they were taken together with 5-FU and leucovorin. In studies, CAPECITABINE TABLETS USP 500 MG was no worse than 5-FU and leucovorin taken together but did not improve survival compared to these two medicines.

breast cancer that has spread to other parts of the body (metastatic breast cancer) together with another medicine called docetaxel (TAXOTERE ®)

breast cancer that has spread to other parts of the body and has not improved after treatment with other medicines such as paclitaxel (TAXOL ®) and anthracycline-containing medicine such as Adriamycin™ and doxorubicin

2. BEFORE YOU TAKE CAPECITABINE TABLET

CAPECITABINE TABLETS USP 500 MG may increase the effect of other medicines used to thin your blood such as warfarin (COUMADIN®). It is very important that your doctor knows if you are taking a blood thinner such as warfarin because CAPECITABINE TABLETS USP 500 MG may increase the effect of this medicine and could lead to serious side effects. If you are taking blood thinners and CAPECITABINE TABLETS USP 500 MG, your doctor needs to check more often how fast your blood clots and change the dose of the blood thinner, if needed.

3. HOW TO TAKE CAPECITABINE TABLET

Take CAPECITABINE TABLETS USP 500 MG exactly as your doctor tells you to. Your doctor will prescribe a dose and treatment plan that is right for you. Your doctor may want you to take both 150 mg and 500 mg tablets together for each dose. If so, you must be able to identify the

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tablets. Taking the wrong tablets could cause an overdose (too much medicine) or underdose (too little medicine). The 150 mg tablets are light peach in color with 150 on one side. The 500 mg tablets are peach in color with 500 on one side. Your doctor may change the amount of medicine you take during your treatment. Your doctor may prescribe CAPECITABINE TABLETS USP 500 MG Tablets with docetaxel (TAXOTERE) injection.

CAPECITABINE TABLETS USP 500 MG is taken in 2 daily doses, a morning dose and an evening dose

Take CAPECITABINE TABLETS USP 500 MG tablets within 30 minutes after the end of a meal (breakfast and dinner)

Swallow CAPECITABINE TABLETS USP 500 MG tablets whole with water

If you miss a dose of CAPECITABINE TABLETS USP 500 MG, do not take the missed dose at all and do not double the next dose. Instead, continue your regular dosing schedule and check with your doctor.

CAPECITABINE TABLETS USP 500 MG is usually taken for 14 days followed by a 7-day rest period (no drug), for a 21-day cycle. Your doctor will tell you how many cycles of treatment you will need.

If you take too much CAPECITABINE TABLETS USP 500 MG, contact your doctor or local poison control center or emergency room right away.

4. POSSIBLE SIDE EFFECTS

The most common side effects of CAPECITABINE TABLETS USP 500 MG are:

diarrhea, nausea, vomiting, sores in the mouth and throat (stomatitis), stomach area pain (abdominal pain), upset stomach, constipation, loss of appetite, and too much water loss from the body (dehydration). These side effects are more common in patients age 80 and older.



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hand-and-foot syndrome (palms of the hands or soles of the feet tingle, become numb, painful, swollen or red), rash, dry, itchy or discolored skin, nail problems, and hair loss

tiredness, weakness, dizziness, headache, fever, pain (including chest, back, joint, and muscle pain), trouble sleeping, and taste problems

These side effects may differ when taking CAPECITABINE TABLETS USP 500 MG with docetaxel (TAXOTERE). Please consult your doctor for possible side effects that may be caused by taking CAPECITABINE TABLETS USP 500 MG with docetaxel (TAXOTERE).

If you are concerned about these or any other side effects while taking CAPECITABINE TABLETS USP 500 MG, talk to your doctor.

Stop taking CAPECITABINE TABLETS USP 500 MG immediately and contact your doctor right away if you have the side effects listed below, or other side effects that concern you. Your doctor can then adjust CAPECITABINE TABLETS USP 500 MG to a dose that is right for you or stop your CAPECITABINE TABLETS USP 500 MG treatment for a while. This should help to reduce the side effects and stop them from getting worse.

Diarrhea: if you have an additional 4 bowel movements each day beyond what is normal or any diarrhea at night

Vomiting: if you vomit more than once in a 24-hour time period

Nausea: if you lose your appetite, and the amount of food you eat each day is much less than usual

Stomatitis: if you have pain, redness, swelling or sores in your mouth

Hand-and-Foot Syndrome: if you have pain, swelling or redness of your hands or feet that prevents normal activity

Fever or Infection: if you have a temperature of 100.5°F or greater, or other signs of infection

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Your doctor may tell you to lower the dose or to stop CAPECITABINE TABLETS USP 500 MG treatment for a while. If caught early, most of these side effects usually improve after you stop taking CAPECITABINE TABLETS USP 500 MG. If they do not improve within 2 to 3 days, call your doctor again. After your side effects have improved, your doctor will tell you whether to start taking CAPECITABINE TABLETS USP 500 MG again and what dose to take. Adjusting the dose of CAPECITABINE TABLETS USP 500 MG to be right for each patient is an important part of treatment.

5. HOW TO STORE CAPECITABINE TABLET

Keep this medicine out of the sight and reach of children.

Store below 30°C and protect from moisture.

6. FURTHER INFORMATION**What Capecitabine 500 mg tablets contains**

The active substance is Capecitabine. Each film coated tablet contains 500 mg of Capecitabine USP.

The other ingredients are Anhydrous lactose USP-NF (Supertab 21 AN), Croscarmellose sodium USP-NF (Ac-Di-Sol), Hypromellose 2910 5CPS USP (Methocel E5 LV Premium), Purified water IH/USP/Ph.Eur, Microcrystalline cellulose USP-NF (Avicel PH 112), Magnesium stearate USP-NF, Opadry Pink 03A84408 IH.

What Capecitabine 500 mg tablets looks like and contents of the pack

Capecitabine 500 mg tablets are peach colored, oval shaped, biconvex, film coated tablets debossed with '3' on one side and 'H' on the other side.

HDPE Container pack: 120's count

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder:**

Name: Hetero Labs Limited

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