

## CAPEHOPE 500

**For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only**

Abbreviated Prescribing information for CAPEHOPE 500 (Capecitabine Tablets I.P.)

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### **PHARMACOLOGICAL PROPERTIES:**

**MECHANISM OF ACTION:** Capecitabine is a non-cytotoxic fluoropyrimidine carbamate, which functions as an orally administered precursor of the cytotoxic moiety 5-fluorouracil (5-FU). Capecitabine is activated via several enzymatic steps. The enzyme involved in the final conversion to 5-FU, thymidine phosphorylase (ThyPase), is found in tumour tissues, but also in normal tissues, albeit usually at lower levels. In human cancer xenograft models capecitabine demonstrated a synergistic effect in combination with docetaxel, which may be related to the upregulation of thymidine phosphorylase by docetaxel.

There is evidence that the metabolism of 5-FU in the anabolic pathway blocks the methylation reaction of deoxyuridylic acid to thymidylic acid, thereby interfering with the synthesis of deoxyribonucleic acid (DNA). The incorporation of 5-FU also leads to inhibition of RNA and protein synthesis. Since DNA and RNA are essential for cell division and growth, the effect of 5-FU may be to create a thymidine deficiency that provokes unbalanced growth and death of a cell. The effects of DNA and RNA deprivation are most marked on those cells which proliferate more rapidly and which metabolise 5-FU at a more rapid rate.

**INDICATIONS:** Capecitabine is indicated for cancer specialists- for treatment of metastatic breast cancer after failure of paclitaxel and anthracycline containing chemotherapy regimen. For first line treatment of advanced gastric cancer in combination with platinum based regimen. For treatment of patients with locally advanced or metastatic breast cancer in combination with docetaxel following failure of cytotoxic chemotherapy. For the treatment of patients with metastatic colorectal cancer.

**DOSAGE AND ADMINISTRATION:** Capecitabine tablets should be swallowed whole with water within 30 minutes after a meal. Do not crush or cut capecitabine tablets. Capecitabine dose is calculated according to body surface area.

**CONTRAINDICATION:** History of severe and unexpected reactions to fluoropyrimidine therapy. Hypersensitivity to capecitabine or to any of the excipients or fluorouracil. Known completed hydroxyrimidine dehydrogenase (DPD) deficiency. During pregnancy and lactation. In patients with severe leukopenia, neutropenia, or thrombocytopenia. In patients with severe hepatic impairment. In patients with severe renal impairment (creatinine clearance below 30 ml/min). Treatment with sorivudine or its chemically related analogues, such as brivudine. If contraindications exist to any of the medicinal products in the combination regimen, that medicinal product should not be used.

**WARNINGS & PRECAUTIONS:** Before taking CAPEHOPE 500, talk to your doctor or pharmacist: if you know that you have a partial deficiency in the activity of the enzyme dihydropyrimidine dehydrogenase (DPD), if you have liver or kidney diseases, if you have or had heart problems (for example an irregular heartbeat or pains to the chest, jaw and back brought on by physical effort and due to problems with the blood flow to the heart), if you have brain diseases (for example, cancer that has spread to the brain, or nerve damage, (neuropathy), if you have calcium imbalances (seen in blood tests), if you have diabetes, if you cannot keep food or water in your body because of severe nausea and vomiting, if you have diarrhea, if you are or become dehydrated, if you have imbalances of ions in your blood (electrolyte imbalances, seen in tests), if you have a history of eye problems as you may need extra monitoring of your eyes, if you have a severe skin reaction.

**DRUG INTERACTIONS:** Before starting treatment, tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is extremely important, as taking more than one medicine at the same time can strengthen or weaken the effect of the medicines. You need to be particularly careful if you are taking any of the following: gout medicines (allopurinol), blood-thinning

medicines (coumarin, warfarin), certain anti-viral medicines (sorivudine and brivudine), medicines for seizures or tremors (phenytoin), interferon alpha, radiotherapy and certain medicines used to treat cancer (folinic acid, oxaliplatin, bevacizumab, cisplatin, irinotecan), medicines used to treat folic acid deficiency.

**ADVERSE REACTIONS:** Diarrhoea, Vomiting, Nausea, Stomatitis, Hand-and-foot skin-reaction, Fever, Infection, Chest pain: Steven-Johnson syndrome, DPD Deficiency.

**MARKETED BY:**



TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)