

COMPOSITION

CAPIXET tablet: Each film coated tablet contains Capecitabine USP 500 mg.

PHARMACOLOGY

Capecitabine is enzymatically converted to 5- fluorouracil (5-FU) in vivo. Both normal and tumor cells metabolize 5-FU to 5-fluoro-2'-deoxyuridine monophosphate (FdUMP) and 5-fluorouridine triphosphate (FUTP). These metabolites cause cell injury by two different mechanisms. First, FdUMP and the folate cofactor, N5-10-methylenetetrahydrofolate, bind to thymidylate synthase (TS) to form a covalently bound ternary complex. This binding inhibits the formation of thymidine from 2'-deoxyuridylate. Thymidylate is the necessary precursor of thymidine triphosphate, which is essential for the synthesis of DNA, so that a deficiency of this compound can inhibit cell division. Second, nuclear transcriptional enzymes can mistakenly incorporate FUTP in place of uridine triphosphate (UTP) during the synthesis of RNA. This metabolic error can interfere with RNA processing and protein synthesis.

INDICATIONS

- Adjuvant Colon Cancer
- Metastatic Colorectal Cancer
- Metastatic Breast Cancer

DOSAGE AND ADMINISTRATION

Take Capecitabine with water within 30 minutes after a meal.

Monotherapy: 1250 mg/m² twice daily orally for 2 weeks followed by a one week rest period in 3-week cycles.

Adjuvant treatment is recommended for a total of 6 months (8 cycles).

In combination with Docetaxel, the recommended dose of Capecitabine is 1250 mg/m² twice daily for 2 weeks followed by a 7-day rest period, combined with Docetaxel at 75 mg/m² as a 1-hour IV infusion every 3 weeks.

Reduce the dose of Capecitabine by 25% in patients with moderate renal impairment.

CONTRAINDICATIONS

- Severe renal impairment
- Hypersensitivity

WARNING & PRECAUTION

Coagulopathy: Monitor anticoagulant response (e.g., INR) and adjust anticoagulant dose accordingly.

Diarrhea: Interrupt Capecitabine treatment immediately until diarrhea resolves or decreases to grade 1.

Cardiotoxicity: Common in patients with a prior history of coronary artery disease.

উবযুক্ষধরতুহ ধহফ জবহধয ঝধরব্বব: Potential risk of acute renal failure secondary to dehydration. Monitor and correct dehydration.

Pregnancy: Can cause fetal harm.

গঁপডুগঁধহবডুঁ ধহফ উবসখগুডুমরপ এডুঁরপরু: Capecitabine should be permanently discontinued in patients who experience a severe mucocutaneous reaction during treatment. Capecitabine may induce hand-and-foot syndrome. Interrupt Capecitabine treatment until the hand-and-foot syndrome event resolves or decreases in intensity.

Hyperbilirubinemia: Interrupt Capecitabine treatment immediately until the hyperbilirubinemia resolves or decreases in intensity.

ঐকসখগুডুমরপ: If grade 3-4 neutropenia or thrombocytopenia occurs, stop therapy until condition resolves.

SIDE EFFECTS

Diarrhea, nausea, vomiting, abdominal pain, Hand-and-foot syndrome, Fatigue/weakness, Hyperbilirubinemia

DRUG INTERACTIONS

If certain medications are combinedly given with Capecitabine there is a possibility for negative drug interactions.

USE IN SPECIFIC POPULATION

Discontinue nursing when receiving Capecitabine treatment.

Monitoring requires for geriatric patients.

Monitoring is recommended in patients with mild to moderate hepatic impairment.

Reduce Capecitabine starting dose in patients with moderate renal impairment.

It is not known whether this drug is excreted in human milk.

PHARMACEUTICAL INFORMATION

Storage

Store below 30°C, in a cool and dry place. Keep away from light. Keep out of the reach of children.

HOW SUPPLIED

CAPIXET tablet: Each HDPE container contains 15 tablets each of which contains Capecitabine 500 mg.

Manufactured by

Everest Pharmaceuticals Ltd.

BSCIC I/A, Kanchpur, Narayanganj, Bangladesh
www.everestpharmabd.com