

CAPECITABINE PCM 500mg

Capecitabine 500 mg

Film-Coated Tablets

1. What CAPECITABINE PCM Is Used For

CAPECITABINE PCM is an anti-cancer medication belonging to the group of medicines known as antimetabolites. It works by interfering with the growth of cancer cells.

It is used for the treatment of the following cancers:

Colorectal Cancer

- Treatment of metastatic colorectal cancer.
- Adjuvant treatment following surgery for colon cancer.

Breast Cancer

- Used for the treatment of metastatic breast cancer after failure of prior chemotherapy.
- In combination with docetaxel for metastatic breast cancer.

Gastric Cancer

- Treatment of advanced gastric cancer in combination with platinum-based chemotherapy.

Esophageal Cancer

- Treatment of locally advanced or metastatic esophageal cancer.

2. Before CAPECITABINE PCM Is Administered to You

CAPECITABINE PCM Should Not Be Used If:

- You are allergic to capecitabine, fluorouracil, or any of its components.
- You have severe kidney problems.
- You have severe liver problems.
- You have a known deficiency of dihydropyrimidine dehydrogenase (DPD).
- You are pregnant or breastfeeding.
- You are currently taking sorivudine or its analogues (such as brivudine).

Special Care Should Be Taken with CAPECITABINE PCM:

- **Hand-Foot Syndrome:** Can cause redness, swelling, and pain on palms and soles.
- **Bone Marrow Suppression:** Can cause reduced blood cell counts leading to infections and bleeding.
- **Kidney Impairment:** Dose adjustments may be required for patients with kidney issues.

- **Liver Impairment:** Dose adjustments may be required for patients with liver issues.
- **Heart Problems:** May cause chest pain or heart attack in some patients.
- **Diarrhea:** Can be severe and requires immediate medical attention.

Pregnancy and Breastfeeding

Pregnancy

- CAPECITABINE PCM can harm an unborn baby and should not be used during pregnancy. Effective contraception must be used.

Breastfeeding

- Do not breastfeed while receiving CAPECITABINE PCM, as it may pass into breast milk.

3. How CAPECITABINE PCM Is Administered to You

Method and Routes of Administration

- Taken orally with water within 30 minutes after a meal.

Dosage

Monotherapy:

- Standard Dose: 1250 mg/m² twice daily (morning and evening) for 14 days, followed by a 7-day rest period (21-day cycle).

Combination Therapy:

- Dose varies based on the treatment regimen and combination partner (typically 800–1000 mg/m² twice daily).

Dose Modifications:

- Doses may be reduced based on tolerability and side effects.
- Elderly patients and those with kidney impairment may require dose adjustments.

Duration of Treatment:

- Treatment continues until disease progression or unacceptable toxicity.

4. Possible Side Effects

Like all medicines, CAPECITABINE PCM can cause side effects. Not everyone experiences them.

Common Side Effects

- **Blood Disorders:** Low white blood cell count (neutropenia), anemia, low platelets (thrombocytopenia).
- **Gastrointestinal Issues:** Nausea, vomiting, diarrhea, abdominal pain, loss of appetite.
- **Hand-Foot Syndrome:** Redness, swelling, numbness, or pain on palms of hands and soles of feet.
- **Skin & Nails:** Dry skin, nail changes, rash.
- **Fatigue:** Tiredness and weakness.

Serious Side Effects (Seek Medical Attention)

- Severe diarrhea (4 or more bowel movements per day).
- Severe hand-foot syndrome (blistering, ulceration).
- Severe infections (high fever, chills).
- Unusual bruising or bleeding.
- Chest pain or heart problems.
- Severe allergic reactions (swelling of face, difficulty breathing).

5. Storing CAPECITABINE PCM

- **Storage Temperature:** Store at room temperature below 25°C.
- **Protection:** Keep in the original container to protect from moisture.
- **Keep Out of Reach:** Store out of reach of children.
- **Expiry:** Do not use after the expiry date printed on the carton.

6. Further Information

Composition

Each film-coated tablet contains:

- **Capecitabine:** 500 mg
- **Other Ingredients:** Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hypromellose, magnesium

stearate, purified talc, titanium dioxide, iron oxide.

Presentation

- Supplied in blister packs:
 - 10 tablets per blister
 - 12 blisters per carton (120 tablets)

Manufactured by:



HHF 280, Industrial Estate, Hal Far,
Birzebbugia BBG 3000, Malta

Imported & Marketed by:



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