Capnib-200
Tablet

Composition: Each film coated tablet contains Capmatinib 200mg as Capmatinib HCl INN.

Pharmacology: Capmatinib is a kinase inhibitor that targets MET, including the mutant variant produced by exon 14 skipping. MET exon 14 skipping results in a protein with a missing regulatory domain that reduces its negative regulation leading to increased downstream MET signaling. Capmatinib inhibited cancer cell growth driven by a mutant MET variant lacking exon 14 at clinically achievable concentrations and demonstrated anti-tumor activity in murine tumor xenograft models derived from human lung tumors with either a mutation leading to MET exon 14 skipping or MET amplification. Capmatinib inhibited the phosphorylation of MET triggered by binding of hepatocyte growth factor or by MET amplification, as well as METmediated phosphorylation of downstream signaling proteins and proliferation and survival of MET-dependent cancer cells.

Indications: It is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA approved test.

Dosage & administration: The recommended dosage of Capnib-200 is 400mg orally twice daily with or without food. Swallow the tablets whole. Do not break, crush or chew the tablets. If a patient misses or vomits a dose, instruct the patient not to make up the dose, but to take the next dose at its scheduled time. Or, as directed by the registered physicians.

Dose Modifications for Adverse Reactions:

Dose Reduction	Dose and Schedule
First	300mg orally twice daily
Second	200mg orally twice daily

Contraindications: It is contraindicated in patients with known hypersensitivity to Capmatinib or any other components of this product.

Precautions: Caution should be exercised when using Capmatinib in patients with risk of Interstitial Lung Disease (ILD)/ Pneumonitis, Risk of Photosensitivity, Hepatotoxicity and Embryo- Fetal Toxicity.

Side effects: The most common side effects are-

- ILD/ Pneumonitis
- Hepatotoxicity

Use in pregnancy & lactation: It can cause fetal harm when administered to a pregnant woman. There are no available data on Capnib-200 use in pregnant women. **Lactation:** There are no data on the presence of Capmatinib or its metabolites in either human or animal milk or its effects on the breastfed child or on milk production. Because of the potential for serious adverse reactions in breastfed children, women should be advised not to breastfeed during treatment with Capmatinib and for 1 week after the last dose.

Use in child: The safety and effectiveness of this drug have not been established in patients less than 18 years of age.

Drug interaction: **Effect of Other Drugs on Capmatinib: Strong CYP3A Inhibitors:** Coadministration of Capmatinib with a strong CYP3A inhibitor increased capmatinib exposure, which may increase the incidence and severity of adverse reactions of Capmatinib, so it should be avoided. **Strong and Moderate CYP3A Inducers:** Coadministration of Capmatinib with a strong CYP3A inducer decreased its exposure. Coadministration of Capmatinib with a moderate CYP3A inducer may also decrease its exposure. Decreases in Capmatinib exposure may decrease its anti- tumor activity, so it should be avoided. **Effect of Capmatinib on Other Drugs: CYP1A2 Substrates:** Coadministration of Capmatinib increased the exposure of a CYP1A2 substrate, which may increase the adverse reactions of these substrates. If coadministration is unavoidable, the CYP1A2 substrate dosage should be decreased in accordance with the approved prescribing information. **P-glycoprotein (P- gp) and Breast Cancer Resistance Protein (BCRP) Substrates:** Coadministration of Capmatinib increased the exposure of a P- gp substrate and a BCRP substrate, which may increase the adverse reactions of these substrates. If coadministration is unavoidable, the P-gp or BCRP substrate dosage should be decreased in accordance with the approved prescribing information. **MATE1 and MATE2K Substrates:** Coadministration of Capmatinib may increase the exposure of MATE1 and MATE2K substrates, which may increase the adverse reactions of these substrates. If coadministration is unavoidable, the MATE1 or MATE2K substrate dosage should be decreased in accordance with the approved prescribing information.

Overdose: No data available.

Storage: Store below 30°C in a dry place, away from sunlight & keep out of reach of children.

Packing: Each box contains 56 tablets in a container.