Erdafixen

Erdafitinib INN

Everest

COMPOSITION

ERDAFIXEN tablet: Each film coated tablet contains Erdafitinib INN 4 mg.

ERDAFIXEN 3 tablet: Each film coated tablet contains Erdafitinib INN 3 mg.

PHARMACOLOGY

Erdafitinib is a kinase inhibitor that binds to and inhibits enzymatic activity of FGFR1, FGFR2, FGFR3 and FGFR4 based on in vitro data. Erdafitinib also binds to RET, CSF1R, PDGFRA, PDGFRB, FLT4, KIT, and VEGFR2. Erdafitinib inhibits FGFR phosphorylation and signaling and decreases cell viability in cell lines expressing FGFR genetic alterations, including point mutations, amplifications, and fusions. Erdafitinib demonstrates antitumor activity in FGFR-expressing cell lines and xenograft models derived from tumor types, including bladder cancer.

INDICATIONS AND USAGE

Erdafitinib is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC) that has-

- Susceptible FGFR3 or FGFR2 genetic alterations and
- Progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

DOSAGE AND ADMINISTRATION

The recommended starting dose of Erdafitinib is 8 mg (two 4 mg tablets) orally once daily, with a dose increase to 9 mg (three 3 mg tablets) once daily based on serum phosphate (PO_4) levels and tolerability at 14 to 21 days. Treatment should be continued until disease progression or unacceptable toxicity occurs.

If a dose of Erdafitinib is missed, it can be taken as soon as possible on the same day. The regular daily dose schedule for Erdafitinib should be resumed the next day. Extra tablets should not be taken to make up for the missed dose.

CONTRAINDICATION

None.

WARNINGS AND PRECAUTIONS

Ocular disorders

Erdafitinib can cause central serous retinopathy/retinal pigment epithelial detachment (CSR/RPED). Monthly ophthalmological examinations should be performed during the first four months of treatment, every 3 months afterwards, and at any time for visual symptoms. When CSR/RPED occurs, Erdafitinib should be withheld and permanently discontinued if it does not resolve within 4 weeks or if Grade 4 in severity.

Hyperphosphatemia

Hyperphosphatemia should be monitored and managed with dose modifications when required.

Embryo-fetal toxicity

Since it can cause fetal harms so patients of the potential risk to the fetus should be advised to use effective contraception.

SIDE EFFECTS

The most common adverse reactions including laboratory abnormalities (≥20%) are elevated phosphate, stomatitis, fatigue, elevated creatinine, diarrhea, dry mouth, nail disorder, elevated alanine aminotransferase, elevated alkaline phosphatase, decrease in sodium, decrease in appetite, decrease in albumin, dysgeusia, decrease in hemoglobin, dry skin, elevated aspartate aminotransferase, decrease in magnesium, dry eye, alopecia, palmar-plantar erythrodysesthesia syndrome, constipation, decrease in phosphate, abdominal pain, elevated calcium, nausea, and musculoskeletal pain.