

ERSTEINE

For the use of Oncologist or a Hospital or a Laboratory

Abbreviated Prescribing information for ERSTEINE (Everolimus 5mg and 10mg) [Please refer the complete prescribing information for details]

PHARMACOLOGICAL PROPERTIES: Everolimus, an inhibitor of mammalian target of rapamycin (mTOR), is an antineoplastic agent.

INDICATIONS: Everolimus is indicated for the treatment of advance renal cell carcinoma.

DOSAGE AND ADMINISTRATION: Everolimus 5mg and 10mg, to be taken once daily at the same time every day. Administer either consistently with food or consistently without food. Everolimus Tablets should be swallowed whole with a glass of water. Do not break or crush tablets.

CONTRAINDICATIONS: Contraindicated in patients with hypersensitivity to the active substance, to other rapamycin derivatives, or to any of the excipients. Hypersensitivity reactions manifested by symptoms including, but not limited to, anaphylaxis, dyspnea, flushing, chest pain, or angioedema (e.g., swelling of the airways or tongue, with or without respiratory impairment).

WARNINGS & PRECAUTIONS: Non-infectious pneumonitis, infections, oral ulceration, renal failure, impaired wound healing, use in geriatric patients, hepatic impairment and during vaccination. Laboratory tests monitoring for renal function, blood glucose and lipids, and hematologic parameters as everolimus alter the value. It is having a potential for embryo-fetal toxicity.

DRUG INTERACTIONS: CYP3A4/PgP inhibitors (ketoconazole, erythromycin and verapamil) and inducers (rifampin, St. John's wort) are significant increases and decrease in everolimus exposure respectively. Drugs that may have their plasma concentrations altered by everolimus: HMG-CoA reductase inhibitors atorvastatin (a CYP3A4 substrate) and pravastatin (a non-CYP3A4 substrate).

ADVERSE REACTIONS: Non-infectious pneumonitis, Infections, Oral ulceration, Renal failure, Impaired wound healing, Stomatitis, Diarrhea, Nausea, Vomiting Constipation, Dry mouth, Fatigue, Edema peripheral, Pyrexia, Asthenia, Infections, Weight decreased, Decreased appetite, Hyperglycemia, Arthralgia, Back pain, Pain in extremity, Dysgeusia, Headache, Insomnia, Cough, Dyspnea, Epistaxis, Pneumonitis, Rash, Pruritus, Alopecia and Hot flush.