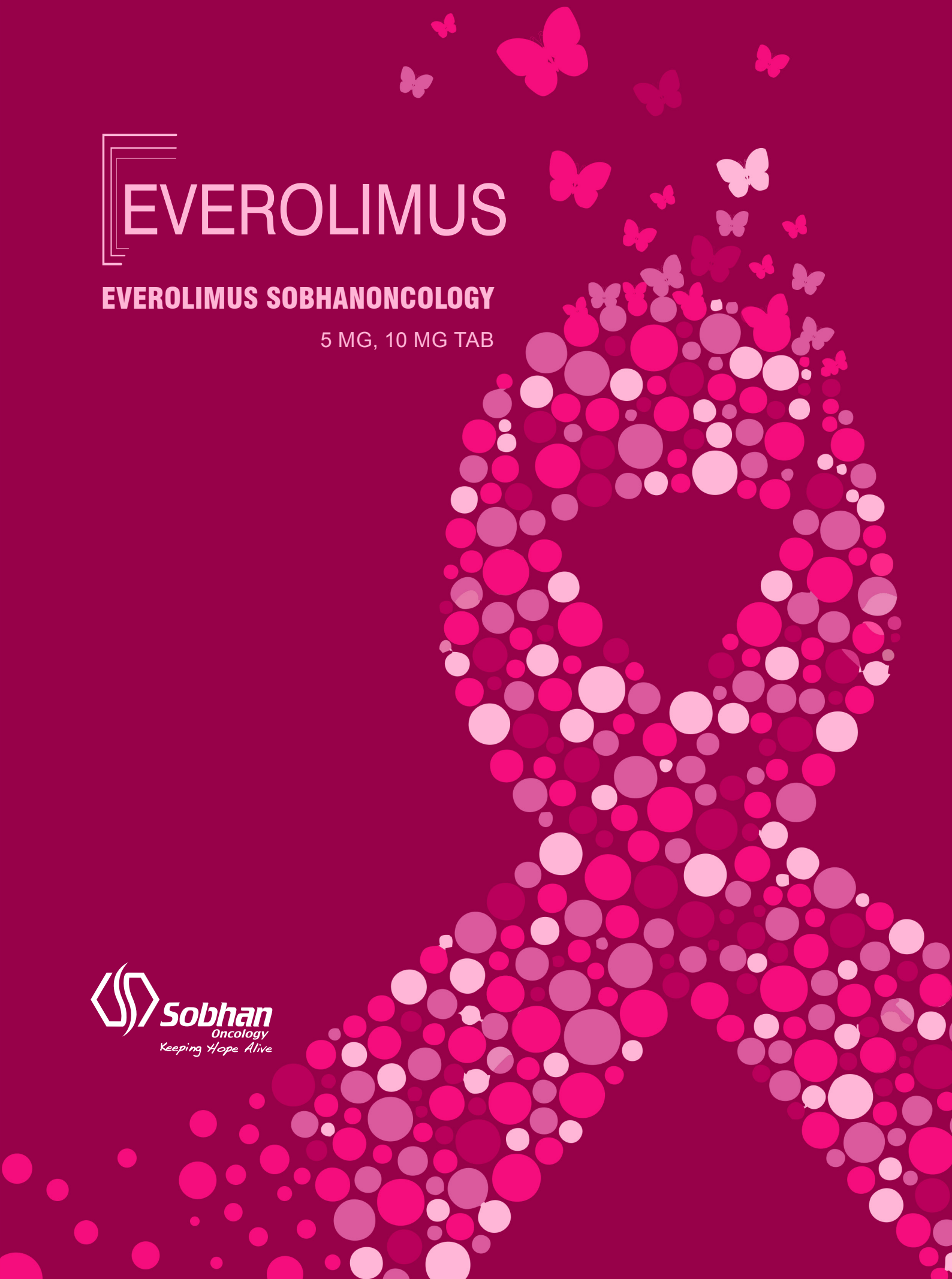
EVEROLIMUS

EVEROLIMUS SOBHANONCOLOGY

5 MG, 10 MG TAB



Sobhan Oncology
Keeping Hope Alive

Everolimus is a kinase inhibitor that inhibits mTOR kinase activity,

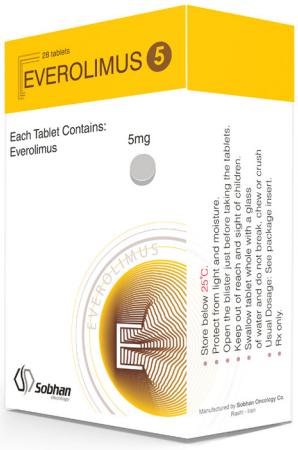
Indicated for the treatment of:

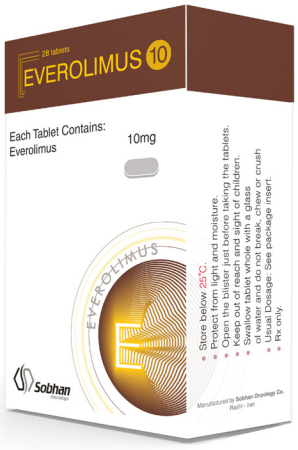
- **Advanced HR+, HER2- Negative Breast Cancer**
- **Advanced Neuroendocrine Tumors of Pancreatic Origin**
- **Progressive, Well-Differentiated, Nonfunctional GI and Lung Neuroendocrine Tumor**
- **Advanced Renal Cell Carcinoma**
- **Renal Angiomyolipoma with Tuberous Sclerosis Complex**
- **SEGA with Tuberous Sclerosis Complex**

Everolimus Sobhanoncology

5 mg, 10 mg Tab

Each box contains 28 tablets in 4 blister pack





HIGHLIGHTS OF PRESCRIBING INFORMATION

INDICATIONS AND USAGE

Everolimus is a kinase inhibitor indicated for the treatment of:

- Postmenopausal women with advanced hormone receptor-positive, HER2 negative breast cancer in combination with exemestane after failure of treatment with letrozole or anastrozole.
- Adults with progressive neuroendocrine tumors of pancreatic origin (PNET) and adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic. Limitation of Use: Everolimus is not indicated for the treatment of patients with functional carcinoid tumors.
- Adults with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib.
- Adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery. Everolimus is kinase inhibitors indicated for the treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected.

DOSAGE AND ADMINISTRATION

Modify the dose for patients with hepatic impairment or for patients taking drugs that inhibit or induce P-glycoprotein (P-gp) and CYP3A4.
Breast Cancer: • 10 mg orally once daily.
NET: • 10 mg orally once daily.
RCC: • 10 mg orally once daily.
TSC-Associated Renal Angiomyolipoma: • 10 mg orally once daily.
TSC-Associated SEGA: • 4.5 mg/m2 orally once daily; adjust dose to attain trough concentrations of 5-15 ng/mL.
TSC-Associated Partial-Onset Seizures: • 5 mg/m2 orally once daily; adjust dose to attain trough concentrations of 5- 15 ng/mL.

DOSAGE FORMS AND STRENGTHS

- EVEROLIMUS: 5 mg, and 10 mg tablets

CONTRAINDICATIONS

Clinically significant hypersensitivity to everolimus or to other rapamycin derivatives.

WARNINGS AND PRECAUTIONS

- Non-Infectious Pneumonitis: Monitor for clinical symptoms or radiological changes. Withhold or permanently discontinue based on severity. • Infections: Monitor for signs and symptoms of infection. Withhold or permanently discontinue based on severity.

Severe Hypersensitivity Reactions: Permanently discontinue for clinically significant hypersensitivity. Angioedema: Patients taking concomitant ACE inhibitors may be at increased risk for angioedema. Permanently discontinue for angioedema. Stomatitis: Initiate dexamethasone alcohol-free mouthwash when starting treatment. Renal Failure: Monitor renal function prior to treatment and periodically thereafter. Impaired Wound Healing: Exercise caution in the peri-surgical period. Geriatric Patients: Monitor and adjust dose for adverse reactions. Metabolic Disorders: Monitor serum glucose and lipids prior to treatment and periodically thereafter. Withhold or permanently discontinue based on severity. Myelosuppression: Monitor hematologic parameters prior to treatment and periodically thereafter. Withhold or permanently discontinue based on severity. Risk of Infection or Reduced Immune Response with Vaccination: Avoid live vaccines and close contact with those who have received live vaccines. Complete recommended childhood vaccinations prior to starting treatment.

Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of reproductive potential of the potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS

Breast cancer, NET, RCC: Most common adverse reactions (incidence ≥ 30%) include stomatitis, infections, rash, fatigue, diarrhea, edema, abdominal pain, nausea, fever, asthenia, cough, headache, and decreased appetite. TSC-Associated Renal Angiomyolipoma: Most common adverse reaction (incidence ≥ 30%) is stomatitis. TSC-Associated SEGA: Most common adverse reactions (incidence ≥ 30%) are stomatitis and respiratory tract infection. TSC-Associated Partial-Onset Seizures: Most common adverse reaction (incidence ≥ 30%) is stomatitis.

DRUG INTERACTIONS

- P-gp and strong CYP3A4 inhibitors: Avoid concomitant use
- P-gp and moderate CYP3A4 inhibitors: Reduce the dose as recommended.
- P-gp and strong CYP3A4 inducers: Increase the dose as recommended.

USE IN SPECIFIC POPULATIONS

For breast cancer, NET, RCC, or TSC-associated renal angiomyolipoma patients with hepatic impairment, reduce the dose. For patients with TSC-associated SEGA or TSC-associated partial-onset seizures and severe hepatic impairment, reduce the starting dose and adjust dose to attain target trough concentrations.

Ref:

Food & Drug Administration, Everolimus Full prescribing Information, Revision 4/2018

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manufacturer of
INJECTABLE
anticancer drugs in Iran

Manufacturing
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Sobhan Oncology

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