LENVIMA® is indicated as monotherapy for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have received no prior systemic therapy

Oral capsules taken once daily

Should be taken at the same time each day

Weight-based dosing:
<60 kg: 8 mg OD
≥60 kg: 12 mg OD

Should be swallowed whole with water or can be dissolved in a tablespoon of water or apple juice

No restrictions about taking with or without food

Treatment should continue as long as clinical benefit is observed or until unacceptable toxicity occurs.

Reference: Lenvima Prescribing Information (approved 21 May 2019)

Abbreviated Prescribing Information:
COMPOSITION: 4 mg hard capsules: Each hard capsule contains lenvatinib mesilate equivalent to 4 mg lenvatinib. 10 mg hard capsules: Each hard capsule contains lenvatinib mesilate equivalent to 10 mg lenvatinib . **PHARMACOLOGY:** Lenvatinib is a receptor tyrosine kinase (RTK) inhibitor that selectively inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors VEGFR1 (FLT1), VEGFR2 (KDR), and VEGFR3 (FLT4), in addition to other proangiogenic and oncogenic pathway-related RTKs including fibroblast growth factor (FGF) receptors FGFR1, 2, 3 and 4, the platelet derived growth factor (PDGF) receptor PDGFRα, KIT, and RET. **INDICATION:** LENVIMA® is indicated for the treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/ Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI). LENVIMA® is indicated in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior vascular endothelial growth factor (VEGF)-targeted therapy. LENVIMA is indicated as monotherapy for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have received no prior systemic therapy. **DOSE AND ADMINISTRATION:** Differentiated Thyroid Cancer (DTC) - The recommended daily dose of lenvatinib is 24 mg taken once daily. Renal Cell Carcinoma (RCC) - The recommended daily dose of lenvatinib is 18 mg once daily in combination with 5 mg of everolimus once daily. HCC - The recommended daily dose of lenvatinib is 8 mg (two 4 mg capsules) once daily for patients with a body weight of < 60 kg and 12 mg (three 4 mg capsules) once daily for patients with a body weight of ≥ 60 kg. Dose adjustments are based only on toxicities observed and not on body weight changes during treatment. The daily dose is to be modified, as needed, according to the dose/toxicity management plan. **WARNINGS AND PRECAUTIONS:** Hypertension, Proteinuria, Hepatotoxicity, Renal failure and impairment, Diarrhoea, Cardiac dysfunction, Posterior reversible encephalopathy syndrome (PRES) / Reversible posterior leucoencephalopathy syndrome (RPLS), Arterial thromboembolisms, Women of childbearing potential, Haemorrhage, Gastrointestinal perforation and fistula formation, Non-Gastrointestinal fistula, QT interval prolongation, Impairment of thyroid stimulating hormone suppression. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients, listed. Breast-feeding. **DRUG INTERATION:** No significant drug-drug interaction is expected between lenvatinib and other CYP3A4/P-gp substrates. Women using oral hormonal contraceptives should add a barrier method. **ADVERSE REACTIONS:** The most frequently reported adverse reactions in the DTC and RCC patient populations (occurring in ≥ 30% of patients) are diarrhoea (80.6%), hypertension (70.1%)*, fatigue (59.7%), decreased appetite (53.7%), decreased weight (52.6%)*, vomiting (48.4%), nausea (45.2%), proteinuria (38.9%)*, stomatitis (36.9%)*, headache (35.8%)*, dysphonia (35.6%)*, palmar-plantar erythrodysaesthesia syndrome (PPE) (34.1%)*, peripheral oedema (33.9%), and hypercholesterolemia (30.6%); the asterisked frequencies are from the DTC patient population. The most frequently reported adverse reactions in HCC (occurring in ≥ 30% of patients) are hypertension (44.0%), diarrhoea (38.1%), decreased appetite (34.9%), fatigue (30.6%), and decreased weight (30.4%). **STORAGE:** Do not store above 30°C. Store in the original blister in order to protect from moisture. **CONTAINER:** Polyamide/ Aluminium/PVC/Aluminium blisters containing 10 capsules. Each carton contains 20 capsules.

โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารกำกับยาและเอกสารอ้างอิง

ใบอนุญาตโฆษณาเลขที่ ฆศ.751/2562

ต้องติดตาม
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Further information is available on request

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