HER-2N (Ribociclib INN) Innerleaf design

Color: Pantone Metallic Coated 8483 C & 185 C

L - 195 mm X W - 255 mm

HER-2N™

Ribociclib Succinate INN

Jenphar Bangladesh | جنفار بنغلاديش

Composition:

HER-2N™ 200 mg Tablet: Each film coated tablet contains Ribociclib succinate INN equivalent to Ribociclib 200 mg.

Pharmacology:

Ribociclib is an inhibitor of cyclin-dependent kinase (CDK) 4 and 6. These kinases are activated upon binding to D-cyclins and play a crucial role in signaling pathways which lead to cell cycle progression and cellular proliferation. The cyclin D- CDK4/6 complex regulates cell cycle progression through phosphorylation of the retinoblastoma protein (pRb). Ribociclib decreases pRb phosphorylation leading to arrest in the G1 phase of the cell cycle and reduces cell proliferation in breast cancer cell lines.

Indication:

Ribociclib is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:

· An aromatase inhibitor as initial endocrine-based therapy; or

· Fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men.

Dose & administration:

The recommended dose of Ribociclib is 600 mg (three 200 mg tablets) taken orally, once daily for 21 consecutive days followed by 7 days off treatment resulting in a complete cycle of 28 days. Ribociclib can be taken with or without food.

Contra-indication:

Ribociclib is contraindicated in patients with known hypersensitivity to this product or any of its components.

Warning and precaution:

Interstitial Lung Disease/Pneumonitis: Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with Ribociclib and other CDK4/6 inhibitors. Monitor patients for pulmonary symptoms indicative of ILD/pneumonitis which may include hypoxia, cough and dyspnea.

Severe Cutaneous Adverse Reactions: Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN) and drug-induced hypersensitivity syndrome (DiHS)/drug reaction with eosinophilia and systemic symptoms (DRESS) can occur.

QT Interval Prolongation: Ribociclib has been shown to prolong the QT interval. Based on the observed QT prolongation during treatment Ribociclib may require dose interruption, reduction or discontinuation. Monitor serum electrolytes (including potassium, calcium, phosphorous and magnesium) prior to the initiation of treatment at the beginning of the first 6 cycles and as clinically indicated.

Increased QT Prolongation with Concomitant Use of Tamoxifen: Ribociclib is not indicated for concomitant use with tamoxifen.

Hepatobiliary Toxicity: Perform liver function tests (LFTs) before initiating therapy with Ribociclib. Monitor LFTs every 2 weeks for first 2 cycles at the beginning of each subsequent 4 cycles and as clinically indicated. Based on the severity of the transaminase elevations, Ribociclib may require dose interruption, reduction or discontinuation.

Neutropenia: Perform complete blood count (CBC) before initiating therapy with Ribociclib. Monitor CBC every 2 weeks for the first 2 cycles, at the beginning of each subsequent 4 cycles and as clinically indicated. Based on the severity of the neutropenia, Ribociclib may require dose interruption, reduction or discontinuation.

Embryo-Fetal Toxicity: Based on findings from animal studies and the mechanism of action, Ribociclib can cause fetal harm when administered to a pregnant woman. Advise women of reproductive potential to use effective contraception during therapy with Ribociclib and for at least 3 weeks after the last dose.

Adverse Effect:

Most common adverse effects (incidence ≥ 20%) are neutropenia, nausea, infections, fatigue, diarrhea, leukopenia, vomiting, alopecia, headache, constipation, rash and cough.

Use in special population:

Pregnancy: Based on findings from animal studies and the mechanism of action, Ribociclib can cause fetal harm when administered to a pregnant woman.

Lactation: It is not known if Ribociclib is present in human milk. There are no data on the effects of Ribociclib on the breastfed infant or on milk production.

Females and Males of Reproductive Potential: Females of reproductive potential should have a pregnancy test prior to starting treatment. Ribociclib may impair fertility in males of reproductive potential.

Pediatric Use: The safety and efficacy of Ribociclib in pediatric patients has not been established.

Geriatric Use: No overall differences in safety or effectiveness of Ribociclib were observed between these patients and younger patients.

Hepatic Impairment: No dose adjustment is necessary in patients with mild hepatic impairment (Child-Pugh A). A reduced starting dose of 400 mg is recommended in patients with moderate (Child-Pugh B) and severe hepatic impairment (Child-Pugh C).

Renal Impairment: No dose adjustment is necessary in patients with mild or moderate renal impairment. Severe renal impairment a starting dose of 200 mg is recommended. Ribociclib has not been studied in breast cancer patients with severe renal impairment.

Drug interaction:

CYP3A4 Inhibitors: Coadministration of a strong CYP3A4 inhibitor (ritonavir) increased Ribociclib exposure. Avoid concomitant use of strong CYP3A inhibitors. If coadministration of Ribociclib with a strong CYP3A inhibitor cannot be avoided, reduce the dose of Ribociclib to 400 mg once daily.

CYP3A4 Inducers: Coadministration of a strong CYP3A4 inducer (rifampin) decreased the plasma exposure of Ribociclib. Avoid concomitant use of strong CYP3A inducers and consider an alternate concomitant medication with no or minimal potential to induce CYP3A.

Overdose:

There are no known cases of overdose with Ribociclib. General symptomatic and supportive measures should be initiated in all cases of overdose where necessary.

Storage:

Store in a cool & dry place below 30° C, protect from light. Keep out of the reach of children.

Packing:

HER-2N™ 200 mg Tablet: Each box contains 21 Film Coated Tablets and one packet silica gel in a sealed HDPE container.

Manufactured by:

Jenphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.

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