Nintib™

Nintedanib Ethanesulfonate INN Capsules

DESCRIPTION

Nintib™ is a preparation of Nintedanib. Nintedanib is a small molecule that inhibits multiple receptor tyrosine kinases (RTKs) and non-receptor tyrosine kinases (nRTKs). Nintedanib inhibits the following RTKs: platelet-derived growth factor receptor (PDGFR) α and β, fibroblast growth factor receptor (FGFR) 1-3, vascular endothelial growth factor receptor (VEGFR) 1-3, colony stimulating factor 1 receptor (CSF1R), and Fms-like tyrosine kinase-3 (FLT-3). These kinases except for FLT-3 have been implicated in pathogenesis of interstitial lung diseases (ILD). Nintedanib binds competitively to the adenosine triphosphate (ATP) binding pocket of these kinases and blocks the intracellular signaling cascades, which have been demonstrated to be involved in the pathogenesis of fibrotic tissue remodeling in ILD. Nintedanib also inhibits the following nRTKs: Lck, Lyn and Src kinases. The contribution of FLT-3 and nRTK inhibition to Nintedanib efficacy in ILD is unknown.

INDICATIONS

Nintib™ is a kinase inhibitor indicated for:

- Treatment of idiopathic pulmonary fibrosis (IPF).
- Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.
- Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

DOSAGE AND ADMINISTRATION

- Recommended dosage: 150 mg twice daily approximately 12 hours apart taken with food.
- Recommended dosage in patients with mild hepatic impairment (ChildPugh A): 100 mg twice daily approximately 12 hours apart taken with food.
- Consider temporary dose reduction to 100 mg, treatment interruption, or discontinuation for management of adverse reactions.
- Prior to treatment initiation, conduct liver function tests in all patients and a pregnancy test in females of reproductive potential.

CONTRAINDICATIONS

None.

SIDE EFFECTS

- Diarrhea, nausea, abdominal pain, vomiting • Liver enzyme elevation
- Decreased appetite • Headache • Weight decreased • Hypertension

PRECAUTIONS AND WARNINGS

Nintib™ is not recommended for use in patients with moderate or severe hepatic impairment. In patients with mild hepatic impairment (Child Pugh A), the recommended dosage is 100 mg twice daily approximately 12 hours apart taken with food. Consider treatment interruption, or discontinuation for management of adverse reactions in these patients.

To be dispensed only by the prescription of a registered physician.

USE IN SPECIAL POPULATION

Pregnancy and Lactation

Based on findings from animal studies and its mechanism of action, Nintedanib can cause fetal harm when administered to a pregnant woman. There are no data on the use of Nintedanib during pregnancy. There is no information on the presence of Nintedanib in human milk, the effects on the breast-fed infant or the effects on milk production. Nintedanib and/or its metabolites are present in the milk of lactating rats. Because of the potential for serious adverse reactions in nursing infants from Nintedanib, advise women that breastfeeding is not recommended during treatment with Nintedanib.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

In phase 3 studies, no overall differences in effectiveness were observed between subjects who were 65 and over and younger subjects; no overall differences in safety were observed between subjects who were 65 and over or 75 and over and younger subjects, but greater sensitivity of some older individuals cannot be ruled out.

Hepatic Impairment

Nintedanib is predominantly eliminated via biliary/fecal excretion (greater than 90%). In a PK study performed in patients with hepatic impairment (Child Pugh A, Child Pugh B), exposure to Nintedanib was increased.

Renal Impairment

Based on a single-dose study, less than 1% of the total dose of Nintedanib is excreted via the kidney. Adjustment of the starting dose in patients with mild to moderate renal impairment is not required. The safety, efficacy, and pharmacokinetics of Nintedanib have not been studied in patients with severe renal impairment (less than 30 mL/min CrCl) and end-stage renal disease.

DRUG INTERACTIONS

Coadministration of P-gp and CYP3A4 inhibitors may increase Nintedanib exposure. Monitor patients closely for tolerability of Nintedanib.

PHARMACEUTICAL PRECAUTIONS

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Nintib™ 100 Capsule:

Box containing 1 blister strip of 10 capsules. Each capsule contains Nintedanib Ethanesulfonate INN equivalent to Nintedanib 100 mg.

Nintib™ 150 Capsule:

Box containing 2 blister strips of 6 capsules each. Each capsule contains Nintedanib Ethanesulfonate INN equivalent to Nintedanib 150 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

TM TRADEMARK

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