Ascentib

Asciminib Hydrochloride INN

Composition

Ascentib 40 Tablet: Each film coated tablet contains Asciminib Hydrochloride INN eqv. to Asciminib 40 mg.

Pharmacology

Asciminib is an ABL/BCR-ABL1 tyrosine kinase inhibitor. Asciminib inhibits the ABL1 kinase activity of the BCRABL1 fusion protein, by binding to the ABL myristoyl pocket. In studies conducted in vitro or in animal models of CML, Asciminib showed activity against wild-type BCR-ABL1 and several mutant forms of the kinase, including the T315I mutation.

Indications

Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs).

Dosage and Administration

The recommended dose of Asciminib is 40 mg twice daily at approximately 12-hour intervals. The recommended dose of Asciminib is taken orally without food. Avoid food consumption for at least 2 hours before and 1 hour after taking Asciminib.

Adverse Reactions

- Myelosuppression
- Pancreatic Toxicity
- Hypertension
- Hypersensitivity
- Cardiovascular Toxicity

Warnings and Precautions

Myelosuppression

Thrombocytopenia, neutropenia, and anemia have occurred in patients receiving Asciminib. Thrombocytopenia occurred in 98 of 356 (28%) patients receiving Asciminib, with Grade 3 or 4 thrombocytopenia reported in 24 (7%) and 42 (12%) of patients, respectively.

Hypertension

Hypertension occurred in 66 of 356 (19%) patients receiving Asciminib, with Grade 3 or 4 hypertension reported in 31 (9%) and 1 (0.3%) patients, respectively. Among the patients with Grade 3 or 4 hypertension, median time to first occurrence was 14 weeks (range, 0.1 to 156 weeks).

Hypersensitivity

Hypersensitivity occurred in 113 of 356 (32%) patients receiving Asciminib, with Grade 3 or 4 hypersensitivity reported in 6 (1.7%) patients. Reactions included rash, edema, and bronchospasm.

Cardiovascular Toxicity

Cardiovascular toxicity (including ischemic cardiac and CNS conditions, arterial thrombotic and embolic conditions) and cardiac failure occurred in 46 (13%) and in 8 (2.2%) of 356 patients receiving Asciminib, respectively.

Contraindications

None.

Use in Specific Populations

Use in Pregnancy

Based on findings from animal studies and the mechanism of action, Asciminib can cause embryo-fetal harm when administered to a pregnant woman. There are no available data on Asciminib use in pregnant women to evaluate a drug associated risk.

Lactation

There are no data on the presence of Asciminib or its metabolites in human milk, the effects on the breastfed child, or milk production.

Pediatric Use

The safety and efficacy of Asciminib in pediatric patients have not been established.

Geriatric Use

In the Asciminib study, 44 of the 233 (19%) patients were 65 years of age or older and 6 (2.6%) were 75 years of age or older.

Storage

Do not store above 25ºC. Protect from light. Keep out of reach of children.

Packaging

Ascentib 40 Tablet: Each HDPE container of Ascentib 40 contains 60's tablet, a silica gel desiccant and polyester coil with a child resistant closure.

P-3637

Manufactured by

ZISKA PHARMA **Ziska Pharmaceuticals Ltd.**

Kaliakoir, Gazipur, Bangladesh

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