Sylvia ODT

Rimegepant Sulfate INN

Composition:
Sylvia ODT: Each orally disintegrating tablet contains Rimegepant Sulfate INN equivalent to Rimegepant 75 mg.

Description:
Rimegepant is an antagonist of the calcitonin gene-related peptide (CGRP) receptor. It competes with CGRP for occupancy at these receptors, preventing the actions of CGRP and its ability to amplify and perpetuate migraine headache pain, ultimately terminating the headache.

Indications:
Sylvia ODT (Rimegepant) is a calcitonin gene-related peptide receptor antagonist indicated for the acute treatment of migraine with or without aura in adults & preventive treatment of episodic migraine in adults.

Dosage & Administration:
Acute Treatment of Migraine- The recommended dose of Sylvia ODT is 75 mg taken orally, as needed. The maximum dose in a 24-hour period is 75 mg. The safety of using more than 18 doses in a 30-day period has not been established.

Preventive Treatment of Episodic Migraine- The recommended dosage of Sylvia ODT is 75 mg taken orally every alternate day.

Contraindications:
Sylvia ODT is contraindicated in patients with a history of hypersensitivity reaction to rimegepant, Sylvia ODT, or any of its components.

Precautions:
Hypersensitivity reactions, including dyspnea and rash, have occurred with Sylvia ODT in clinical studies. Hypersensitivity reactions can occur days after administration, and delayed serious hypersensitivity has occurred. If a hypersensitivity reaction occurs, discontinue Sylvia ODT and initiate appropriate therapy.

Side effects:
Allergic reactions, including trouble breathing and rash, can happen after you taking Sylvia ODT. The most common side effects of Sylvia ODT are: nausea, stomach pain & indigestion.

Use in specific population:

Pregnancy
There are no adequate data on the developmental risk associated with the use of Sylvia ODT in pregnant women.

Lactation
There are no data on the presence of rimegepant or its metabolites in human milk, the effects of rimegepant on the breastfed infant, or the effects of rimegepant on milk production.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

Geriatric Use
In pharmacokinetic studies, no clinically significant pharmacokinetic differences were observed between elderly and younger subjects.

Hepatic Impairment
No dosage adjustment of Sylvia ODT is required in patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment. Plasma concentrations of rimegepant were significantly higher in subjects with severe (Child-Pugh C) hepatic impairment. Avoid use of Sylvia ODT in patients with severe hepatic impairment.

Renal Impairment
No dosage adjustment of Sylvia ODT is required in patients with mild, moderate, or severe renal impairment. Sylvia ODT has not been studied in patients with end-stage renal disease and in patients on dialysis. Avoid use of Sylvia ODT in patients with end-stage renal disease (CLcr < 15 mL/min).

Drug interactions:

CYP3A4 Inhibitors
Concomitant administration of Sylvia ODT with strong inhibitors of CYP3A4 results in a significant increase in rimegepant exposure. Avoid concomitant administration of Sylvia ODT with strong inhibitors of CYP3A4. Concomitant administration of Sylvia ODT with moderate inhibitors of CYP3A4 may result in increased exposure of rimegepant. Avoid another dose of Sylvia ODT within 48 hours when it is concomitantly administered with moderate inhibitors of CYP3A4.

CYP3A Inducers
Concomitant administration of Sylvia ODT with strong or moderate inducers of CYP3A can result in a significant reduction in rimegepant exposure, which may lead to loss of efficacy of Sylvia ODT. Avoid concomitant administration of Sylvia ODT with strong or moderate inducers of CYP3A.

P-gp Inhibitors
Concomitant administration of Sylvia ODT with potent inhibitors of P-gp (e.g., amiodarone, cyclosporine, lapatinib, quinidine, ranolazine) may result in increased exposure of rimegepant. Avoid another dose of Sylvia ODT within 48 hours when it is concomitantly administered with potent inhibitors of P-gp.

Overdosage:
There is limited clinical experience with Rimegepant overdosage. Treatment of an overdose of Rimegepant should consist of general supportive measures including monitoring of vital signs and observation of the clinical status of the patient. No specific antidote for the treatment of rimegepant overdose is available. Rimegepant is unlikely to be significantly removed by dialysis because of high serum protein binding

Storage:
Do not store above 25°C. Protect from light. Keep out of reach of children.

Packaging:
Sylvia ODT: Each box contains 1X4's tablet in blister pack.

Manufactured by
ZISKA PHARMA
Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh

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