

Gefapix™ 45

Gefapixant 45 mg

Composition

Gefapix™ 45 Tablet: Each film coated tablet contains Gefapixant 45 mg as Gefapixant Citrate INN.

Pharmacology

Gefapixant is a selective antagonist of the P2X3 receptor. P2X3-containing receptors belong to the family of purinergic receptors and are ATP-dependent ion channels, which are also located on sensory C-fibers of the vagus nerve in the airways. C-fibers are activated in response to inflammation or chemical irritants. Under inflammatory conditions, ATP is released by mucosal cells of the respiratory tract. The binding of extracellular ATP to P2X3 receptors is recognized by C-fibers as a damage signal and is perceived as a coughing stimulus, which in turn triggers a cough reflex. Gefapixant blocks ATP-mediated activation of P2X3 receptors, which are thought to be responsible for chronic cough.

Indication

Gefapix™ 45 Tablet is indicated in adults for the treatment of refractory chronic cough or unexplained chronic cough.

Dosage & Administration

Adult patients: One 45 mg tablet orally twice daily with or without food.

If a patient misses a dose, he/she should skip that dose and take the next dose at the regularly scheduled time.

Contraindication

Severe hypersensitivity reaction to Gefapixant Citrate or any of the ingredients.

Warnings & Precaution

Gefapixant should be used with caution in patients with known hypersensitivity to sulfonamides.

Side Effects

Very common side effects are dysgeusia, ageusia, hypogeusia. Frequent side effects are upper respiratory tract infections, decreased appetite, taste disturbance, dizziness, nausea, diarrhea, dry mouth, hypersalivation, epigastric pain, dyspepsia, oral hypoesthesia, oral paresthesia etc. Occasionally, urinary stones, bladder stones, nephrolithiasis are seen.

Use in Pregnancy & Lactation

The use of Gefapixant in women during pregnancy has not been studied, as a precautionary measure, the use of Gefapix during pregnancy and in women of childbearing potential who do not use contraception is not recommended. It is not known whether Gefapixant is present in human breast milk, affects milk formation, or has an effect on breastfed infants. Gefapixant has been detected in milk in animal studies.

Fertility: There are no clinical data on the effects of Gefapixant on fertility in humans. Animal studies showed no impairment of fertility.

Use in Elderly Patients

No dose adjustment of Gefapixant due to age is required and no age-specific differences in the efficacy or safety of Gefapixant has been established. This medicine is essentially excreted by the kidneys. Since older patients are more likely to have impaired renal function, the risk of adverse effects may be higher in these patients. Caution should be exercised at the initial dosing frequency.

Use in Paediatric Population

The safety and efficacy of Gefapixant have not been established in patients below 18 years of age.

Use in Special Population

Obstructive sleep apnea: Gefapixant should not be used in patients with refractory chronic cough or unexplained chronic cough with comorbid obstructive sleep apnea.

Patients with liver disease: Gefapixant has not been studied in patients with hepatic impairment.

Patients with renal impairment: The recommended dose of Gefapixant in patients with severe impaired (eGFR < 30 mL/minute/1.73 m²) renal function on non-dialysis is one 45 mg tablet once daily with or without food. No dose adjustment is required in patients with mild or moderate renal impairment (eGFR ≥ 30 mL/minute/1.73 m²).

Effect on driving ability and on the use of machines: Patient may experience dizziness after using Gefapixant, which may affect the ability to drive and use machines.

Drug Interactions

Effect of proton pump inhibitor: Concomitant use of the proton pump inhibitor omeprazole had no clinically meaningful effect on the pharmacokinetics of Gefapixant.

Potential influence of Gefapixant on other medicines: Based on in vitro studies, the potential of Gefapixant for CYP inhibition or induction is low.

Effect of Gefapixant on other medicines: No clinically dependent drug interactions have been identified.

Effect of other medicines on Gefapixant: No clinically meaningful drug interactions have been identified.

Overdose

Patient should be observed for adverse reactions and appropriate symptomatic treatment should be initiated. Gefapixant is partially removed by hemodialysis.

Storage

Store below 30°C in a dry place. Keep away from light. Keep out of reach of children.

How supplied

Gefapix™ 45 Tablet: Each box contains 20 tablets in Alu-PVDC Blister pack.

Manufactured by:



SQUARE
PHARMACEUTICALS PLC.
Salgaria, Pabna, Bangladesh

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