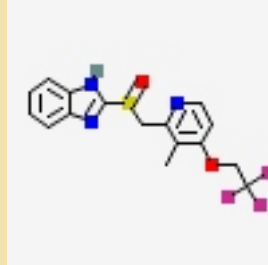


Lansoprazole (Cas No 103577-45-3)



Lansoprazole

The active ingredient in Lansoprazole Delayed-Release Capsules, Lansoprazole for Delayed-Release Oral Suspension and Lansoprazole SoluTab Delayed-Release Orally Disintegrating Tablets is lansoprazole, a substituted benzimidazole, 2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl] methyl] sulfinyl] benzimidazole, a compound that inhibits gastric acid secretion. Its empirical.

Lansoprazole is a white to brownish-white odorless crystalline powder which melts with decomposition at approximately 166°C. Lansoprazole is freely soluble in dimethylformamide; soluble in methanol; sparingly soluble in ethanol; slightly soluble in ethyl acetate, dichloromethane and acetonitrile; very slightly soluble in ether; and practically insoluble in hexane and water.

Lansoprazole is stable when exposed to light for up to two months. The rate of degradation of the compound in aqueous solution increases with decreasing pH. The degradation half-life of the drug substance in aqueous solution at 25°C is 18 hours at pH 7.0.

Lansoprazole is supplied in delayed-release capsules, in delayed-release orally disintegrating tablets for oral administration and in a packet for delayed-release oral suspension.

The delayed-release capsules are available in two dosage strengths: 15 mg and 30 mg of lansoprazole per capsule. Each delayed-release capsule contains enteric-coated granules consisting of 15 mg or 30 mg of lansoprazole (active ingredient) and the following inactive ingredients: hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, colloidal silicon dioxide, magnesium carbonate, methacrylic acid copolymer, starch, talc, sugar sphere, sucrose, polyethylene glycol, polysorbate 80, and titanium dioxide. Lansoprazole SoluTab Delayed-Release Orally Disintegrating Tablets are available in two dosage strengths: 15 mg and 30 mg of lansoprazole per tablet. Each delayed-release orally disintegrating tablet contains enteric-coated microgranules consisting of 15 mg or 30 mg of lansoprazole (active ingredient) and the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, magnesium carbonate, hydroxypropyl cellulose, hypromellose, titanium dioxide, talc, mannitol, methacrylic acid, polyacrylate, polyethylene glycol, glyceryl monostearate, polysorbate 80, triethyl citrate, ferric oxide, citric acid, crospovidone, aspartame **, artificial strawberry flavor and magnesium stearate. Lansoprazole for Delayed-Release Oral Suspension are available in two dosage strengths: 15 mg and 30 mg of lansoprazole per packet. Each packet of delayed-release oral suspension contains enteric-coated granules consisting of 15 or 30 mg of lansoprazole (active ingredient) and the following inactive ingredients (inactive granules): confectioner's sugar, mannitol, docusate sodium, crospovidone, citric acid, sodium citrate, magnesium stearate, and artificial strawberry flavor. The lansoprazole granules and inactive granules, present in unit dose packets, are constituted with water to form a suspension and consumed orally.