

Sun Pharmaceutical Industry Gets CDSCO Panel Nod To Study Fexuprazan HCL Tablet For Erosive Esophagitis

New Delhi: Responding to the proposal presented by the Sun Pharmaceutical Industry to manufacture and market the Fexuprazan Hydrochloride tablet, the Subject Expert Committee (SEC) functional under the Central Drug Standard Control Organisation (CDSCO) has approved the firm for conducting the bioequivalence study of the proposed drug.

This came after Sun Pharmaceutical Industry presented their proposal for a grant of permission to manufacture and market Fexuprazan Hydrochloride tablets, 40 mg, indicated for the treatment of erosive esophagitis (EE) along with the bioequivalence study protocol vide protocol No. 052/23 Version-00, Dated: 22.01.2024, before the committee.

Erosive esophagitis (EE) is an erosion of the esophageal epithelium due to chronic irritation. It can be caused by a number of factors but is primarily a result of gastroesophageal reflux disease (GERD). The main symptoms of EE are heartburn and regurgitation; other symptoms can include epigastric pain, odynophagia, dysphagia, nausea, chronic cough, dental erosion, laryngitis, and asthma. Symptoms can be exacerbated by eating certain trigger foods or when lying down.

Fexuprazan is a newly developed potassium-competitive acid blocker (P-CAB), which inhibits acid generation and secretion in a competitive and reversible manner.

Fexuprazan, a novel potassium-competitive acid blocker, reversibly suppresses the K⁺/H⁺-ATPase enzyme in proton pumps within gastric parietal cells. Fexuprazan's suppression of gastric acid was maintained in healthy individuals for 24 hours in a dose-dependent manner.

Completed clinical trials of fexuprazan have demonstrated comparable efficacy to PPIs for the healing of erosive esophagitis and the relief of GERD-related esophageal symptoms without concern for safety signals. Ongoing clinical trials are evaluating fexuprazan for the prevention of NSAID-induced peptic ulcer disease, non-erosive GERD, and acute and chronic gastritis, as well as the healing efficacy and maintenance of erosive esophagitis (EE).

At the recent SEC meeting for gastroenterology and hepatology held on July 25, 2024, the expert panel reviewed the proposal for the grant of permission to manufacture and market Fexuprazan hydrochloride tablets (40 mg) indicated for the treatment of erosive esophagitis (EE) along with the bioequivalence study protocol of the drug major Sun Pharma.

After detailed deliberation, the committee recommended the grant of permission to conduct the bioequivalence study as per the protocol presented by the firm.

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