P-CAB (potassium-competitive acid blocker) overcomes the drawbacks of PPI, which is an existing gastric acid secretion inhibitor, and reversibly binds to the proton pump, suppresses gastric acid secretion, has high stability against gastric acid, and acts directly on the proton pump rather than as a pro-drug. Thereby, this is opening the market for a new gastric acid secretion inhibitor, based on its advantages such as rapid onset of action, powerful effect, long half-life, and the ability to administer the drug without affecting meals. Substances such as Vonoprazan and Tegoprazan have been commercialized, and are mainly used to treat gastric acid-related diseases, especially gastroesophageal reflux disease (GERD).

Nevertheless, since injections for P-CAB preparations has not been developed, there have been difficulties in administering it to patients who need faster effects than oral drugs or who cannot take the oral drugs.

"1-(5-(2,4-difluorophenyl)-1-((3-fluorophenyl)sulfonyl)-4-methoxy-1H-pyrrol-3-yl)-N-methylmethanamine", named fexuprazan, is a compound described in Korean Patent No. 10-1613245, and has excellent antiulcer activity (i.e., proton pump inhibitory activity, etc.) and Helicobacter pylori (H. pylori) eradication activity and GPCR inhibition activity, whereby it is known to be useful for prevention and treatment of gastrointestinal tract ulcers, gastritis, reflux esophagitis, or gastrointestinal damage caused by Helicobacter pylori.

It is known that fexuprazan has therapeutic effects on diseases associated with gastric acid secretion, specifically gastroesophageal reflux disease (GERD), and more specifically, erosive esophagitis (EE), when orally administered at a dose of 40 mg once a day.

Therefore, the present inventors have developed a fexuprazan injection composition and conducted intensive research on the composition, and found an appropriate dosage regimen for each indication of the fexuprazan injection composition, thereby completing the present invention.

[DETAILED DESCRIPTION OF THE INVENTION]

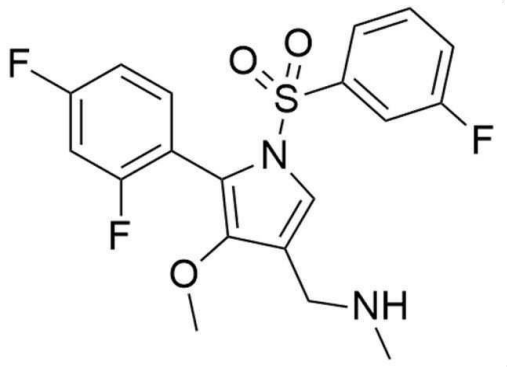
[Technical Problem]

It is an object of the present invention to provide an appropriate dosage regimen for each indication of a fexuprazan injection composition.

[Technical Solution]

In order to achieve the above object, according to the present invention, there is provided an injection composition for preventing or treating gastrointestinal disease in which a compound represented by the following Chemical Formula 1 or a pharmaceutically acceptable salt thereof is administered at a dose of 0.4 to 0.6 times the dose at which the therapeutic effect for oral administration was confirmed:

[Chemical Formula 1]



The chemical name of the compound represented by Chemical Formula 1 is 1-(5-(2,4-difluorophenyl)-1-((3-fluorophenyl)sulfonyl)-4-methoxy-1H-pyrrol-3-yl)-N-methylmethanamine, which is a compound described in Korean Patent No. 10-1613245.

The above compound is an active ingredient that exhibits pharmacological effects of the injection composition according to the present invention, and has excellent anti-ulcer activity (i.e., proton pump inhibitory activity, etc.), Helicobacter pylori (H. pylori) eradication activity and GPCR inhibition action, and thus is useful in the prevention and treatment of gastrointestinal tract ulcer, gastritis, reflux esophagitis, or gastrointestinal damage caused by Helicobacter pylori.

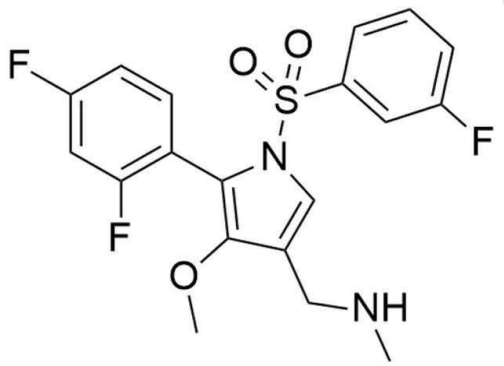
Further, the above compound as well as a pharmaceutically acceptable salt of the compound can also be used in the present invention. As salts, salts commonly

[CLAIMS]

[Claim 1]

Use of an injection composition in the manufacture of a medicament for preventing or treating gastrointestinal disease in which the injection composition comprises a compound represented by the following Chemical Formula 1 or a pharmaceutically acceptable salt thereof, wherein the compound is to be administered in an amount of 10 mg to 30 mg once a day:

[Chemical Formula 1]

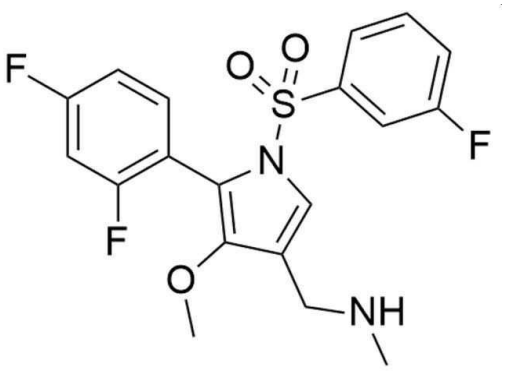


wherein the gastrointestinal disease is chosen amongst gastrointestinal tract ulcers, gastritis, reflux esophagitis, gastrointestinal damage caused by Helicobacter pylori, and erosive esophagitis.

[Claim 2]

Use of an injection composition in the manufacture of a medicament for treating bleeding in which the injection composition comprises a compound represented by the following Chemical Formula 1 or a pharmaceutically acceptable salt thereof, wherein the compound is to be administered in an amount of 70 mg to 90 mg once a day, or 30 mg to 50 mg twice a day:

[Chemical Formula 1]

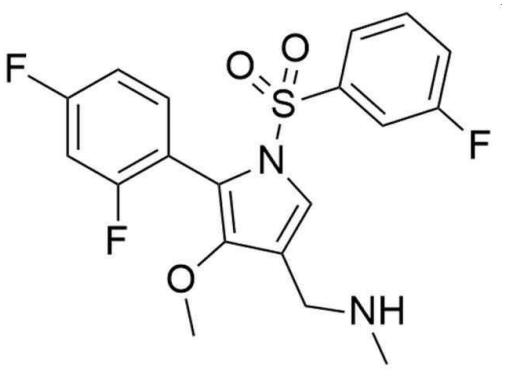


wherein the bleeding is caused by peptic ulcers or by iatrogenic ulcers after endoscopic procedures.

[Claim 3]

Use of an injection composition in the manufacture of a medicament for preventing bleeding in which the injection composition comprises a compound represented by the following Chemical Formula 1 or a pharmaceutically acceptable salt thereof, wherein the compound is to be administered in an amount of 30 mg to 50 mg, and then maintained and administered at 1 mg/h to 10 mg/h for 24 hours or more:

[Chemical Formula 1]



wherein the bleeding is caused by peptic ulcers or by iatrogenic ulcers after endoscopic procedures.