ALOPRIM® (alloprun sodium) for Injection

500 mg
(p-al-p-rin)

For Intravenous Infusion Only

DESCRIPTION: ALOPRIM (alloprun sodium) for injection is the brand name for alloprun, a sodium carbonate inhibitor. ALOPRIM (alloprun sodium) for injection is a sterile solution for intravenous infusion only. It is supplied as a mouth of alloprun equivalent to 500 mg alloprun (ALOPRIM (alloprun sodium)) for injection containing no preservatives.

The chemical name for alloprun is 1,5-dihydro-4H-pyrano[2,3-d]pyrimidine-4-one monocarboxylic acid. It is a white to yellowish-white, odorless, and slightly effervescent dry powder which is odorless.

ALOPRIM (alloprun sodium) for injection contains no preservatives.

CLINICAL PHARMACOLOGY: ALOPRIM acts on the parietal cells without histamine stimulation. ALOPRIM (alloprun sodium) for injection reduces the amount of acid secreted by the stomach and inhibits the biochemical reactions immediately preceding its formation. The degree of this decrease is dose dependent.

Alloprun is a structural analogue of the natural base, hydrazine. As an inhibitor of stomach, the effects may last for many hours after the end of the treatment. The inhibitory effect of ALOPRIM (alloprun sodium) for injection on pepsinogen and pepsin activity has not been determined.

The pharmacokinetics of Aloprim and alloprun are similar. In healthy human volunteers, the plasma concentration vs. time profile of Aloprim following a single oral dose of 500 mg of aloprun (ALOPRIM) is linear with respect to dose.

Preclinical studies have shown that ALOPRIM (alloprun sodium) for injection does not cause any significant changes in the levels of systemic and intracellular pH or in the activities of acid-related enzymes.

Tea leaves containing Aloprim or Aloprun (ALOPRIM (alloprun sodium) for injection) did not cause any significant changes in the levels of systemic and intracellular pH or in the activities of acid-related enzymes.

ALOPRIM (alloprun sodium) for injection is contraindicated in patients with known hypersensitivity to drugs of this class.

Indications: Aloprim is indicated for the treatment of patients with ulcerative colitis and Crohn’s disease.

INFORMATION FOR PATIENTS: ALOPRIM (alloprun sodium) for injection contains no preservatives.

WARNINGS: ALOPRIM (alloprun sodium) for injection should be used cautiously in patients with a history of renal or hepatic disease, or in those with a history of alcoholism, or in patients receiving concomitant therapy with drugs known to cause hepatic or renal impairment.

PREGNANCY: Aloprim is not expected to cause fetal harm when administered to pregnant women. Aloprun is classified as pregnancy category C. Aloprun should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

LACTATION: It is not known whether Aloprim is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Aloprun is administered to a nursing woman.

ADVERSE REACTIONS: Aloprim is generally well tolerated; however, some patients may experience minor side effects such as headache, dizziness, nausea, vomiting, constipation, or diarrhea.

The most common adverse reactions associated with Aloprim therapy are headache, dizziness, nausea, vomiting, constipation, and diarrhea. Aloprun is classified as pregnancy category C. Aloprun should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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