



## IBUPROFEN/FAMOTIDINE (Duexis®) UTILIZATION MANAGEMENT CRITERIA

**DRUG CLASS:** Combination Non-Steroidal Anti-Inflammatory Drug (NSAID) and Histamine-2 (H2) Blocker

**BRAND (generic) NAMES:** Ibuprofen/Famotidine (Duexis) tablets 800 mg / 26.6 mg

### FDA-APPROVED INDICATIONS

Duexis is indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal (GI) ulcer, which in the clinical trials was defined as a gastric and/or duodenal ulcer in patients who are taking ibuprofen for those indications. The clinical trials primarily enrolled patients less than 65 years of age without a prior history of GI ulcer.

### COVERAGE AUTHORIZATION CRITERIA for ibuprofen/famotidine

- 1) Patient must be treated for osteoarthritis or rheumatoid arthritis.
- 2) Patient must be 18 years of age or older.
- 3) Patient must meet at least one of the following criteria:
  - a) Age 60 years or greater;
  - b) History of peptic ulcer disease or ulcer/GI bleeding related to NSAIDs;
  - c) Current regimen includes anticoagulant, prescription antiplatelet drug, corticosteroid or DMARD (disease-modifying and anti-rheumatic drug) therapy (e.g., methotrexate);
  - d) Hereditary or acquired coagulation defect (e.g., hemophilia, Von Willebrand's disease, protein C or S deficiency, thrombocytopenia or chronic renal failure).

### BLACK BOX WARNINGS

#### Cardiovascular Risk

Ibuprofen, a component of Duexis, may increase the risk of serious cardiovascular (CV) thrombotic events, myocardial infarction, and stroke, which can be fatal. Risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. Duexis is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.

#### Gastrointestinal Risk

Nonsteroidal anti-inflammatory drugs (NSAIDs), including ibuprofen, a component of Duexis, increase the risk of serious gastrointestinal (GI) adverse reactions including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. Reactions can occur at any time without warning symptoms. Elderly patients are at greater risk.

**RATIONALE:**

Traditional NSAIDs are considered safe, effective and appropriate for short-term therapy in patients with low risk of developing gastrointestinal ulcers or bleeding. Duexis is only indicated for treatment of the chronic conditions osteoarthritis and rheumatoid arthritis, and to decrease the risk of developing upper gastrointestinal ulcers.

**DOSAGE AND ADMINISTRATION:**

One tablet three times daily.

Not recommended in moderate/severe renal insufficiency (creatinine clearance < 50 ml/min).

**REFERENCES:**

Ibuprofen/famotidine (Duexis). Product Information. Horizon Pharma USA, Inc. 2011.

Lanza FL, et al. Members of the Practice Parameters Committee of the American College of Gastroenterology. Am J Gastroenterol 2009; 104:728 – 738; doi: 10.1038/ajg.2009.115; published online 24 February 2009.