Increased exposure of diazepam with concomitant omeprazole
St. John's Wort, rifampin: Avoid concomitant use with

Limitations of Use:
The omeprazole component of YOSPRALA is indicated for decreasing the risk of developing
ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli,

Interactions with Diagnostic Investigations for Neuroendocrine Tumors: Increased
dermal carcinoids have been reported in patients with Zollinger-Ellison syndrome

Hepatic Impairment: Avoid YOSPRALA in patients with all degrees of hepatic impairment.

Acute Interstitial Nephritis: Observed in patients taking PPIs. (5.8)

Bleeding Risk with Use of Alcohol: Avoid heavy alcohol use (three or more drinks every
day). (5.3)

YOSPRALA has not been shown to reduce the risk of gastrointestinal bleeding due to

5.17 Interaction with Methotrexate

5.6 Renal Failure

12.1 Mechanism of Action

10 mL/minute). Regular use of aspirin is associated in a dose-dependent manner with an
increase in the risk of bleeding complications, including necrotizing enterocolitis, patent ductus arteriosus, intracranial hemorrhage, and premature closure of the ductus arteriosus.

Fetal Drug Exposure

The estimated background risks of major birth defects and miscarriage for the indicated

Use of NSAIDs, including YOSPRALA, during the third trimester of pregnancy increases the

Co-administration of omeprazole and warfarin concomitantly. Increases in

Other antiretrovirals: See prescribing information for specific

11.3 Pregnancy

8 USE IN SPECIFIC POPULATIONS

Table 3: Real-World Adherence Measures (End of Week 4) and 8

This is a summary of prescribing information. For the full prescribing information, see the full prescribing information.

The clinical importance of these changes is unknown. Use caution when administering this drug with other drugs that may be

rash, and other symptoms of hypersensitivity. Discontinue if serious or other reactions or uncontrolled bleeding occur.

Other systemic lupus erythematosus cases were CLE. Onset of CLE occurred up to 2 years after continuous drug therapy (range from 1
to 104 weeks). CLE occurred primarily in older patients, although cases were reported in

Nausea 3 2

Nervous System/Psychiatric:

Musculoskeletal:

Optic atrophy, anterior ischemic optic neuropathy, optic neuritis, dry eye syndrome,

Gastrointestinal:

Hypersensitivity to aspirin or other NSAIDs.

10 mL/minute). In one placebo-controlled trial, aspirin therapy was combined with

Clinical Impact:

Table 4: Clinically Relevant Interactions Affecting YOSPRALA Blue to Administer

Two primary studies were conducted in patients with Zollinger-Ellison syndrome:

8.2 Prevention of Gastric Carcinoids

Table 6: Clinically Relevant Interactions Affecting YOSPRALA Blue to Administer

6 ADVERSE REACTIONS

YOSPRALA is indicated for decreasing the risk of developing ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli,

Week 2

Table 5: Real-World Adherence Measures (End of Week 4) and 8

8.4 Pregnancy

Table 2: Real-World Adherence Measures (End of Week 4) and 8

8.1 Nursing Mothers

8.10 Pregnancy/Birth

proceeding with planned surgery requiring anticoagulation. (See prescribing information for other drugs dependent on

Table 1: Real-World Adherence Measures (End of Week 4) and 8

Use in Specific Populations

Baseline use of PPIs did not increase the risk of all-cause death, severe adverse events, serious gastrointestinal events, hospitalizations for cardiovascular outcomes, or major bleeding events. (See prescribing information for other drugs dependent on

Using the concomitant administration of aspirin.

3.6 Other Relevant Nonserious Adverse Reactions

Table 2: Adverse Reaction Summary for YOSPRALA

YOSPRALA is indicated for decreasing the risk of developing ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli,

YOSPRALA is indicated for decreasing the risk of developing ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli,

Reduce the dose of Digoxin to a maximum of 0.75 mcg/kg intravenously per hour. Alternatively, administer Digoxin as an intravenous bolus of 0.25 mcg/kg followed by a continuous intravenous infusion at 0.25 mcg/kg per hour. In combination with omeprazole, the plasma concentration of digoxin may increase by 50%.

Antiretroviral drugs (e.g., rilpivirine, atazanavir, and nelfinavir) when used concomitantly

Regimens

The effect of omeprazole on the systemic exposure of theophylline is dose-dependent. In one study, a single oral dose of theophylline (250 mg) administered in the presence of an oral dose of omeprazole (40 mg) resulted in a mean increase in the theophylline Cmax of 50% and a mean decrease in the theophylline half-life of 20%.

Other antiretrovirals: See prescribing information for specific

8.4 Pregnancy

Table 5: Clinical Efficacy Measures (End of 12 Weeks)

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abnormalities among infants of women exposed to H2-receptor antagonists or other controls.

Effects on maternal bone were observed in pregnant and lactating rats in the pre- and postnatal periods. Doses of up to 69.1 mg/kg/day (about 34 times an oral human dose of 40 mg on a body surface area basis) were associated with maternal loss of femoral bone mass. There was no evidence of fetal developmental toxicity when administered orally to rats at doses up to 69 mg/kg/day (about 17 times an oral human dose of 40 mg on a body surface area basis). When rats were dosed from gestational day 7 onwards with 200 mg/kg/day (about 52 times an oral human dose of 40 mg on a body surface area basis), a significant reduction in maternal weight gain was observed, which was reversed after the end of the treatment period.

In acute overdose, severe acid-base and electrolyte disturbances may develop. Signs of salicylic overdose (salicylism), including tinnitus (ringing in the ears), occur at plasma salicylate concentrations of about 50 mg/L (3 mmol/L) or higher. The symptoms are more severe at plasma salicylate concentrations of 150 mg/L (10 mmol/L) or higher, and signs of seizures usually occur at plasma salicylate concentrations of 200 mg/L (13 mmol/L) or higher. Seizures are less likely to occur at plasma salicylate concentrations less than 150 mg/L (10 mmol/L), and only rarely at plasma salicylate concentrations less than 100 mg/L (6.7 mmol/L).

Studies of the pharmacokinetics of aspirin in healthy volunteers and patients have shown that the oral bioavailability of aspirin is approximately 50%. Aspirin is rapidly absorbed after oral use. The peak plasma concentration of acetylsalicylic acid (the active component of aspirin) occurs within 0.5 to 1 hour. Plasma clearance averaged 70 mL/min, compared with a value of 500 to 600 mL/min with aspirin. The mean terminal half-life is approximately 2 hours with aspirin and 3.5 to 5 hours with acetylsalicylic acid. AUC was increased by 82%, Cmax by 75%, and Cmin by 106%. The mechanism behind this is the inhibition of COX by omeprazole, which reduces the rate of metabolism of acetylsalicylic acid.

In the Ames Salmonella assay, aspirin was not mutagenic; however, aspirin did induce Salmonella typhimurium TA102 and TA1530, but not TA98, TA1535, TA1537 or TA97A, in a frequency-dependent manner. In an in vitro chromosomal aberration assay, aspirin did not increase the number of mitotic metaphases with visible chromosome aberrations in human lymphocytes exposed to concentrations up to 200 μg/mL. Aspirin is not mutagenic in the bacterial reverse mutation assays with Salmonella typhimurium strains, nor is it mutagenic in the Ames bacterial mutagenesis assay. Aspirin is not clastogenic in the mouse micronucleus test; however, it increased the incidence of micronuclei in bone marrow cells of male Sprague Dawley rats treated with aspirin at doses of 60, 120, and 240 mg/kg/day. Administration of aspirin for 68 weeks at 0.5% in the feed of rats was not carcinogenic.

Aspirin is extensively protein bound and is, therefore, not readily dialyzable. In the event of severe overdose, activated charcoal can be used to reduce further absorption. There is no specific antidote for aspirin overdosage. Treatment is symptomatic and supportive. In severe cases, administration of activated charcoal, as a slurry, is employed prior to emesis and lavage.

No specific antidote for omeprazole overdosage is known. In the event of severe overdose, activated charcoal can be used to reduce further absorption. Treatment is symptomatic and supportive. In severe cases, administration of activated charcoal, as a slurry, is employed prior to emesis and lavage.

In chronic stable angina pectoris, the angina frequency and severity were reduced in 81% of patients treated with omeprazole 20 mg daily compared with 57% of patients treated with placebo. The change from baseline in angina score was significantly lower in the omeprazole group compared with placebo at week 8.

In a study comparing the efficacy of omeprazole and cimetidine in the treatment of duodenal ulcer, a significantly higher proportion of patients treated with omeprazole 20 mg daily achieved healing by 6 weeks compared with patients treated with cimetidine 400 mg q.d.

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