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Kapidex Delayed Release Capsules (Dexlansoprazole Delayed Release Capsules)

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Clinical Trials Experience

The safety of KAPIDEX (dexlansoprazole delayed release capsules) was evaluated in 4548 patients in controlled and uncontrolled clinical studies, including 863 patients treated for at least 6 months and 203 patients treated for one year. Patients ranged in age from 18 to 90 years (median age 48 years), with 54% female, 85% Caucasian, 8% Black, 4% Asian, and 3% other races. Six randomized controlled clinical trials were conducted for the treatment of EE, maintenance of healed EE, and symptomatic GERD, which included 896 patients on placebo, 455 patients on KAPIDEX (dexlansoprazole delayed release capsules) 30 mg, 2218 patients on KAPIDEX (dexlansoprazole delayed release capsules) 60 mg, and 1363 patients on lansoprazole 30 mg once daily.

As clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Most Commonly Reported Adverse Reactions

The most common adverse reactions (? 2%) that occurred at a higher incidence for KAPIDEX (dexlansoprazole delayed release capsules) than placebo in the controlled studies are presented in Table 2.

Table 2: Incidence of Treatment-Emergent Adverse Reactions in Controlled Studies

Lansoprazole 30 mg (N=1363) %	KAPIDEX (dexlansoprazole delayed release capsules) Total (N=2621) %	KAPIDEX (dexlansoprazole delayed release capsules) 60 mg (N=2218) %	KAPIDEX (dexlansoprazole delayed release capsules) 30 mg (N=4 55) %	Placebo (N=896) %	Adverse Reaction
3.2	4.8	4.7	5.1	2.9	Diarrhea
2.6	4.0	4.0	3.5	3.5	Abdominal Pain
1.8	2.9	2.8	3.3	2.6	Nausea
0.8	1.9	1.7	2.9	0.8	Upper Respiratory Tract Infection
1.1	1.6	1.4	2.2	0.8	Vomiting
1.2	1.6	1.4	2.6	0.6	Flatulence

Adverse Reactions Resulting in Discontinuation

In controlled clinical studies, the most common adverse reaction leading to discontinuation from KAPIDEX (dexlansoprazole delayed release capsules) therapy was diarrhea (0.7%).

Other Adverse Reactions

Other adverse reactions that were reported in controlled studies at an incidence of less than 2% are listed below by body system:

anemia, lymphadenopathy ***Blood and Lymphatic System Disorders:***

angina, arrhythmia, bradycardia, chest pain, edema, myocardial infarction, palpitation, tachycardia ***Cardiac Disorders:***

ear pain, tinnitus, vertigo ***Ear and Labyrinth Disorders:***

goiter ***Endocrine Disorders:***

eye irritation, eye swelling ***Eye Disorders:***

abdominal discomfort, abdominal tenderness, abnormal feces, anal discomfort, Barrett's esophagus, bezoar, bowel sounds abnormal, ***Gastrointestinal Disorders:*** breath odor, colitis microscopic, colonic polyp, constipation, dry mouth, duodenitis, dyspepsia, dysphagia, enteritis, eructation, esophagitis, gastric polyp, gastritis, gastroenteritis, gastrointestinal disorders, gastrointestinal hypermotility disorders, GERD, GI ulcers and perforation, hematemesis, hematochezia, hemorrhoids, impaired gastric emptying, irritable bowel syndrome, mucus stools, nausea and vomiting, oral mucosal blistering, painful defecation, proctitis, paresthesia oral, rectal hemorrhage

adverse drug reaction, asthenia, chest pain, chills, feeling abnormal, inflammation, mucosal inflammation, ***General Disorders and Administration Site Conditions:*** nodule, pain, pyrexia

biliary colic, cholelithiasis, hepatomegaly ***Hepatobiliary Disorders:***

hypersensitivity ***Immune System Disorders:***

candida infections, influenza, nasopharyngitis, oral herpes, pharyngitis, sinusitis, viral infection, vulvo-vaginal infection ***Infections and Infestations:***

falls, fractures, joint sprains, overdose, procedural pain, sunburn ***Injury, Poisoning and Procedural Complications:***

ALP increased, ALT increased, AST increased, bilirubin decreased/increased, blood creatinine increased, blood gastrin increased, ***Laboratory Investigations:*** blood glucose increased, blood potassium increased, liver function test abnormal, platelet count decreased, total protein increased, weight increase

appetite changes, hypercalcemia, hypokalemia ***Metabolism and Nutrition Disorders:***

arthralgia, arthritis, muscle cramps, musculoskeletal pain, myalgia ***Musculoskeletal and Connective Tissue Disorders:***

altered taste, convulsion, dizziness, headaches, migraine, memory impairment, paresthesia, psychomotor hyperactivity, tremor, ***Nervous System Disorders:*** trigeminal neuralgia

abnormal dreams, anxiety, depression, insomnia, libido changes ***Psychiatric Disorders:***

dysuria, micturition urgency ***Renal and Urinary Disorders:***

dysmenorrhea, dyspareunia, menorrhagia, menstrual disorder ***Reproductive System and Breast Disorders:***

aspiration, asthma, bronchitis, cough, dyspnoea, hiccups, hyperventilation, respiratory tract congestion, sore ***Respiratory, Thoracic and Mediastinal Disorders:*** throat

acne, dermatitis, erythema, pruritis, rash, skin lesion, urticaria ***Skin and Subcutaneous Tissue Disorders:***

deep vein thrombosis, hot flush, hypertension ***Vascular Disorders:***

Additional adverse reactions that were reported in a long-term uncontrolled study and were considered related to KAPIDEX (dexlansoprazole delayed release capsules) by the treating physician included: anaphylaxis, auditory hallucination, B-cell lymphoma, central obesity, cholecystitis acute, decreased hemoglobin, dehydration, diabetes mellitus, dysphonia, epistaxis, folliculitis, gastrointestinal pain, gout, herpes zoster, hyperglycemia, hyperlipidemia, hypothyroidism, increased neutrophils, MCHC decrease, neutropenia, oral soft tissue disorder, rectal tenesmus, restless legs syndrome, somnolence, thrombocythemia, tonsillitis.

Other adverse reactions not observed with KAPIDEX (dexlansoprazole delayed release capsules) , but occurring with the racemate lansoprazole can be found in the lansoprazole package insert, ADVERSE REACTIONS section.

Postmarketing Experience

Adverse reactions have been identified during post-approval of KAPIDEX (dexlansoprazole delayed release capsules) . As these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

blurred vision ***Eye Disorders:***

oral edema ***Gastrointestinal Disorders:***

facial edema ***General Disorders and Administration Site Conditions:***

anaphylactic shock (requiring emergency intervention), ***Immune System Disorders:***

Stevens-Johnsons syndrome, toxic epidermal necrolysis (some fatal)

pharyngeal edema, throat tightness ***Respiratory, Thoracic and Mediastinal Disorders:***

generalized rash, leucocytoclastic vasculitis ***Skin and Subcutaneous Tissue Disorders:***