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Balsalazide Disodium (Giazo)

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Clinical Trials Experience

Because 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.

The data described below reflect exposure of GIAZO in 565 ulcerative colitis patients with mildly to moderately active disease. GIAZO was evaluated in one placebocontrolled trial (168 treated with GIAZO), one active-controlled trial (210 treated with GIAZO); and a subset of these patients also participated in an uncontrolled, open-label, extension study (additional 187 treated with GIAZO). The population studied had a mean age of 43.1 (range: 18-80) years; approximately 94% of patients were < 65 years old, 49% were male, and 84% were white.

In the placebo-controlled trial, the most common adverse reactions with GIAZO in male patients were headache, nasopharyngitis, anemia, diarrhea, fatigue, pharyngolaryngeal pain, and urinary tract infection. 10% of patients in the GIAZO group and 13% of patients in the placebo group discontinued treatment due to an adverse reaction. The majority of adverse reactions were mild to moderate in severity. The most common serious adverse reactions in both the placebo and GIAZO groups were gastrointestinal disorders, which were mainly associated with symptoms of ulcerative colitis.

Adverse reactions occurring in at least 2% of male patients and at a rate numerically higher than placebo in the placebo-controlled trial are listed in Table 1.

-Table 1: Adverse Reactions Experienced by at Least 2% of GIAZO –Treated Male Patients and at a Rate Numerically Greater than Placebo in a Placebo Controlled Trial

PLACEBO N=37	GIAZO 6.6 g/day N=82	Adverse Reaction
0%	3.7%	Anemia
0%	3.7%	Diarrhea
0%	3.7%	Pharyngolaryngeal Pain
0%	3.7%	Urinary Tract Infection
0%	2.4%	Arthralgia
0%	2.4%	Insomnia
0%	2.4%	Musculoskeletal Pain

Data collected from all three trials (placebo-controlled, active-controlled, and openlabel) showed that female patients reported adverse reactions more frequently than did male patients (76% and 66%, respectively).

The following adverse reactions, presented by body system, were reported by less than 1% of GIAZO-treated ulcerative colitis patients in controlled trials.

increased blood pressure, increased heart rate **Cardiovascular and Vascular:**

erythema nodosum, rash **Dermatological:**

dyspnea **Respiratory, Thoracic and Mediastinal Disorders:**

abdominal pain, constipation, defecation urgency, diarrhea, dry mouth, hard feces, flatulence, gastroesophageal reflux disease, **Gastrointestinal Disorders:**
vomiting

increased aspartate aminotransferase **Hepatobiliary Disorders:**

gastroenteritis, upper respiratory infection **Infections and Infestations:**

arthralgia, back pain, myalgia **Musculoskeletal and Connective Tissue Disorders:**

dizziness, lethargy **Nervous System Disorders:**

face edema, fatigue, malaise, pain, pyrexia, swelling **General Disorders and Administrative Site Disorders:**

Postmarketing Experience

Because these reactions are reported voluntarily from a population of unknown size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These adverse reactions have been chosen for inclusion due to a combination of seriousness, frequency of reporting, or potential causal connection to products which contain or are metabolized to mesalamine, including balsalazide.

myocarditis, pericarditis, vasculitis **Cardiovascular and Vascular:**

alveolitis, pleural effusion, pneumonia (with and without eosinophilia) **Respiratory:**

pancreatitis **Gastrointestinal:**

interstitial nephritis, renal failure. **Renal:**

elevated liver enzymes (AST, ALT, GGT, LDH, alkaline phosphatase), elevated bilirubin, jaundice, cholestatic jaundice, cirrhosis, **Hepatobiliary Disorders:**
hepatocellular damage including liver necrosis and liver failure, Kawasaki-like syndrome including hepatic dysfunction. Some of these cases were fatal.

alopecia, pruritus **Dermatological:**