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Alinia (Nitazoxanide)

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Alinia (nitazoxanide) Tablets: In controlled and uncontrolled clinical studies of 1,628 HIV-uninfected patients age 12 years and older who received various dosage regimens of Alinia (nitazoxanide) Tablets, the most common adverse events reported regardless of causality assessment were: abdominal pain (6.7%), diarrhea (4.3%), headache (3.1%) and nausea (3.1%). In placebo-controlled clinical trials using the recommended dose, the rates of occurrence of these events did not differ significantly from those of the placebo. In placebo-controlled trials of HIV-uninfected patients age 12 years and older who received Alinia (nitazoxanide) Tablets for the treatment of diarrhea caused by *Giardia lamblia*, approximately 1% of patients discontinued therapy because of an adverse event.

Adverse events occurring in less than 1% of the patients age 12 years and older participating in clinical trials of Alinia (nitazoxanide) Tablets are listed below:

***Body as a Whole*:** asthenia, fever, pain, allergic reaction, pelvic pain, chills, chills and fever, flu syndrome.
***Nervous System*:** dizziness, somnolence, insomnia, tremor, hypesthesia.
***Digestive System*:** vomiting, dyspepsia, anorexia, flatulence, constipation, dry mouth, thirst.
***Urogenital System*:** discolored urine, dysuria, amenorrhea, metrorrhagia, kidney pain, edema labia.
***Metabolic & Nutrition*:** increased SGPT.
***Hemic & Lymphatic Systems*:** anemia, leukocytosis.
***Skin*:** rash, pruritus.
***Special Senses*:** eye discoloration, ear ache.
***Respiratory System*:** epistaxis, lung disease, pharyngitis.
***Cardiovascular System*:** tachycardia, syncope, hypertension.
***Muscular System*:** myalgia, leg cramps, spontaneous bone fracture.

Alinia (nitazoxanide) for Oral Suspension: In controlled and uncontrolled clinical studies of 613 HIV-uninfected pediatric patients who received Alinia (nitazoxanide) for Oral Suspension, the most frequent adverse events reported regardless of causality assessment were: abdominal pain (7.8%), diarrhea (2.1%), vomiting (1.1%) and headache (1.1%). These were typically mild and transient in nature. In placebo-controlled clinical trials, the rates of occurrence of these events did not differ significantly from those of the placebo. None of the 613 pediatric patients discontinued therapy because of adverse events.

Adverse events occurring in less than 1% of the pediatric patients participating in clinical trials of Alinia (nitazoxanide) for Oral Suspension are listed below:

***Digestive System*:** nausea, anorexia, flatulence, appetite increase, enlarged salivary glands.
***Body as a Whole*:** fever, infection, malaise.
***Metabolic & Nutrition*:** pruritus, sweat. *Skin:* increased creatinine, increased SGPT.
***Special Senses*:** eye discoloration (pale yellow).
***Respiratory System*:** rhinitis.
***Nervous System*:** dizziness.
***Urogenital System*:** discolored urine.

The adverse events seen in adult patients treated with Alinia (nitazoxanide) for Oral Suspension were similar to those observed in adult patients treated with Alinia (nitazoxanide) Tablets.