

## **17 PATIENT COUNSELING INFORMATION**

### **17.1 Important Precautions Regarding COLAZAL**

- Instruct patients not to take COLAZAL if they have a hypersensitivity to salicylates (e.g., aspirin).
- Patients should be instructed to contact their health care provider under the following circumstances:
  - If they experience a worsening of their ulcerative colitis symptoms.
  - If they are diagnosed with pyloric stenosis, because COLAZAL capsules may be slow to pass through their digestive tract.
  - If they are diagnosed with renal dysfunction. Damage to the kidney has been observed in people given medications similar to COLAZAL.

### **17.2 What Patients Should Know About Adverse Reactions**

- In adult clinical trials the most common adverse reactions were headache, abdominal pain, diarrhea, nausea, vomiting, respiratory infection, and arthralgia.
- In the pediatric clinical trial the most common adverse reactions were headache, abdominal pain, vomiting, diarrhea, ulcerative colitis, nasopharyngitis, and pyrexia.
- Inform patients that this listing of adverse reactions is not complete and not all adverse reactions can be anticipated. If appropriate, a more comprehensive list of adverse reactions can be discussed with patients.

### **17.3 What Patients Should Know About Taking COLAZAL with Other Medication**

- Drug interactions with COLAZAL have not been studied.

Manufactured for Salix Pharmaceuticals, Inc., Morrisville, NC 27560

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