



Patient Information Sheet

Balsalazide Disodium (marketed as Colazal)

This is a summary of the most important information about Colazal. For details, talk to your healthcare professional.

What is Colazal used for?

Colazal is used to treat the signs and symptoms of mild to moderately active ulcerative colitis in patients 5 years of age and older. The safety and efficacy of Colazal are not known after 12 weeks in adults and 8 weeks in children (ages 5-17 years).

Who should not take Colazal?

You should not take Colazal if you are allergic to medicines containing:

- salicylates, such as aspirin
- mesalamine (Rowasa®, Asacol®, or Pentasa®)

General Precautions with Colazal:

Some people experience a worsening of their colitis symptoms possibly related to the use of Colazal.

What should I tell my doctor or healthcare provider?

Tell your doctor or healthcare provider if you have kidney disease or a history of kidney problems. Patients taking products that contain the same active ingredient as Colazal have sometimes had kidney problems.

Tell your healthcare provider if you are trying to become pregnant, are already pregnant, or are breast-feeding.

Tell your healthcare provider if you have pyloric stenosis, a narrowing of the muscle that controls the emptying of the stomach.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may affect how Colazal works or Colazal may affect how your other medicines work.

What are some possible side effects of Colazal? *(This is NOT a complete list of side effects reported with Colazal. Your healthcare provider can discuss with you a more complete list of side effects.)*

Common side effects include:

- Headache
- Stomach pain
- Nausea
- Diarrhea

Reports of patients' experience with similar products:

In patients taking products that contain the same active ingredient as Colazal (mesalamine), several serious liver-related side effects have been reported, including abnormal liver function tests, jaundice, cirrhosis, liver damage, and liver failure. It is not possible to determine how often these side effects occur or whether these events are directly related to the active ingredient.

For more detailed information about Colazal, ask your healthcare provider.

