Crofelemer delayed-release tablets

MEDICATION GUIDE

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine talk to your doctor, pharmacist, or health care provider.

What is this medicine?

CROFELEMER (kroe FEL e mer) is used to treat diarrhea. It is helpful for treating diarrhea due to HIV-infection or AIDS.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

How should I use this medicine?

Take this medicine by mouth with or without food. Swallow the tablets whole. Do not cut, crush or chew this medicine. Follow the directions on the prescription label. Take your doses at regular intervals. Do not take your medicine more often than directed.

Talk to your pediatrician regarding the use of this medicine in children. Special care may be needed.

Overdosage: If you think you've taken too much of this medicine contact a poison control center or emergency room at once.

What if I miss a dose?

If you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

What should I tell my health care provider before I take this medicine?

They need to know if you have any of these conditions:
- Pancreatitis
- Recent travel abroad or suspected food poisoning
- Stomach or intestine problems
- An unusual or allergic reaction to crofelemer, other medicines, foods, dyes, or preservatives
- Pregnant or trying to get pregnant
- Breast-feeding

What may interact with this medicine?

Interaction information is not available.

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible:
- Allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
- Bloody or watery diarrhea
- Pain when urinating
- Severe constipation
- Stomach pain

Side effects that usually do not require medical attention (Report these to your doctor or health care professional if they continue or are bothersome.):
- Back pain
- Bloating
- Cold symptoms
- Cough
- Gas
- Joint pain
- Muscle pain
- Nausea

This list may not describe all possible side effects. Call your
doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I watch for while using this medicine?
Visit your doctor for regular check ups. Tell your doctor if your symptoms do not get better or if they get worse.
Stop taking this medicine and call your doctor or go to the nearest hospital emergency room right away if you develop unusual or severe stomach-area (abdominal) pain, especially if you also have bright red, bloody stools or black stools that look like tar.

Where should I keep my medicine?
Keep out of the reach of children.
Store at room temperature between 15 and 30 degrees C (59 and 86 degrees F). Protect from light. Keep container tightly closed. Throw away any unused medicine after the expiration date.

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