

Mytesi[®]

(crofelemer) 125 mg
delayed-release tablets

IMPORTANT PATIENT INFORMATION

This is only a summary. See complete Prescribing Information at Mytesi.com or by calling 1-844-722-8256. This does not take the place of talking with your doctor about your medical condition or treatment.

What Is Mytesi (crofelemer)?

Mytesi is a prescription medicine used to improve symptoms of noninfectious diarrhea (diarrhea not caused by a bacterial, viral, or parasitic infection) in adults living with HIV/AIDS on ART.

Do Not Take Mytesi if you have diarrhea caused by an infection. Before you start Mytesi, your doctor and you should make sure your diarrhea is not caused by an infection (such as bacteria, virus, or parasite).

Possible Side Effects of Mytesi Include:

- Upper respiratory tract infection (sinus, nose, and throat infection)
- Bronchitis (swelling in the tubes that carry air to and from your lungs)
- Cough
- Flatulence (gas)
- Increased bilirubin (a waste product when red blood cells break down)

For a full list of side effects, please talk to your doctor. Tell your doctor if you have any side effect that bothers you or does not go away.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Should I Take Mytesi If I Am:

Pregnant or Planning to Become Pregnant?

- Studies in animals show that Mytesi could harm an unborn baby or affect the ability to become pregnant
- There are no studies in pregnant women taking Mytesi
- This drug should only be used during pregnancy if clearly needed

A Nursing Mother?

- It is not known whether Mytesi is passed through human breast milk
- If you are nursing, you should tell your doctor before starting Mytesi
- Your doctor will help you to decide whether to stop nursing or to stop taking Mytesi

Under 18 or Over 65 Years of Age?

- Mytesi has not been studied in children under 18 years of age
- Mytesi studies did not include many people over the age of 65. So it is not clear if this age group will respond differently. Talk to your doctor to find out if Mytesi is right for you

What Should I Know About Taking Mytesi With Other Medicines?

If you are taking any prescription or over-the-counter medicine, herbal supplements, or vitamins, tell your doctor before starting Mytesi.

What If I Have More Questions About Mytesi?

For more information, please see the full Prescribing Information at Mytesi.com or speak to your doctor or pharmacist.

To report side effects or make a product complaint or for additional information, call 1-844-722-8256.

Rx Only

Manufactured by Patheon, Inc.
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Mytesi comes from the *Croton lechleri* tree harvested in South America.

