Each rectal suppository contains:
Mesalamine, USP 1000 mg
Inactive Ingredient: Hard Fat

Adult Dosage: One (1000 mg) rectal suppository daily. See accompanying prescribing information.

Store below 25°C (77°F). May be refrigerated.

Keep away from direct heat, light or humidity.
Keep this and all medication out of the reach of children.
Keep container tightly closed.

Rx only 30 Rectal Suppositories (5 Strips of 6)

Manufactured by:
Halo Pharmaceuticals Incorporation
Whippany, NJ 07931 U.S.A.

Manufactured for:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

HL:9230:30C:R1

Mylan.com
Mesalamine Rectal Suppositories

For Rectal Use Only

PHARMACIST: Dispense the accompanying Patient Information Leaflet to each patient.

Each rectal suppository contains:

Mesalamine, USP 1000 mg
Inactive Ingredient: Hard Fat

Adult Dosage:
One (1000 mg) rectal suppository daily. See accompanying prescribing information.

Store below 25°C (77°F). May be refrigerated. Keep away from direct heat, light or humidity.

Keep this and all medication out of the reach of children.

Keep container tightly closed.

Manufactured by:
Halo Pharmaceuticals Incorporation
Whippany, NJ 07891 U.S.A.

Manufactured for:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

Mylan.com
MESALAMINE
RECTAL SUPPOSITORY
1000 mg
Store below 25°C (77°F). May be refrigerated.

Mfd. for: Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

HL:9230:1S:R1
These highlights do not include all the information needed to use mesalamine rectal suppositories safely and effectively. See full prescribing information for mesalamine rectal suppositories.

INDICATIONS AND USAGE
Mesalamine rectal suppositories are indicated for the treatment of mild to moderately active ulcerative proctitis.

DOSAGE AND ADMINISTRATION
1.1 Mesalamine rectal suppositories should be inserted using the applicator supplied with the product.

1.2 If more than one mesalamine rectal suppository is required at the same time, separate them by at least 1 hour to reduce the risk of an overdose.

ADVERSE REACTIONS
Hypersensitivity Reactions
Mesalamine-induced exacerbations of cutaneous lupus erythematosus and systemic lupus erythematosus have been reported.

Drug-Laboratory Test Interactions
There have been no documented reports of serious toxicity in man resulting from massive overdosing with mesalamine.
What are the possible side effects of mesalamine rectal suppositories?

• After a mesalamine rectal suppository is inserted in your rectum, you should try to

Use mesalamine rectal suppositories exactly as prescribed by your doctor. Your doctor

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when

Tell your doctor about all the medicines you take, 

• are pregnant or plan to become pregnant. It is not known if mesalamine can harm

It is not known if mesalamine rectal suppositories are safe and effective for use for

It is not known if mesalamine rectal suppositories are safe and effective in children.

Who should not use mesalamine rectal suppositories?

Do not use mesalamine rectal suppositories if you are:

• allergic to medicines that contain salicylates, including aspirin.

• Mesalamine rectal suppositories are a prescription medicine used to treat active ulcerative proctitis (inflammation of the rectum) in adults. It is not known if mesalamine rectal suppositories are effective and safe for use for

It is not known if mesalamine rectal suppositories are safe and effective in children.

The most common side effects of mesalamine rectal suppositories include:

• fever

• infection

• rash

• Inflammation of the sac around the heart (pericarditis). Tell your doctor right away if you get chest pain or shortness of breath. Your doctor may tell you to stop using mesalamine rectal suppositories if you get pericarditis. 

Tell your doctor about any medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I use mesalamine rectal suppositories?

• Once mesalamine rectal suppositories exactly as prescribed by your doctor. Your doctor 

• Mesalamine rectal suppositories can cause diarrhea of surfaces including, clothing and other fabrics, flooring, painted surfaces, marble, granite, vinyl and enamel. Keep mesalamine rectal suppositories away from these surfaces to prevent staining. 

What are the possible side effects of mesalamine rectal suppositories?

Mesalamine suppositories may cause serious side effects, including:

• Allergic type reactions. This can include sudden symptoms called “acute intolerance syndrome.” Some people who use mesalamine rectal suppositories for the first time can have an allergic reaction to medications containing sulfasalazine. Stop using mesalamine rectal suppositories and tell your doctor away if you get any of these symptoms:

• cramps

• stomach (abdominal) pain

• bloody diarrhea

• fever

• headache

• rash

• Inflammation of the sac around the heart (pericarditis). Tell your doctor right away if you get chest pain or shortness of breath. Your doctor may tell you to stop using mesalamine rectal suppositories if you get pericarditis.

Tell your doctor about any medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I store mesalamine rectal suppositories?

• Store mesalamine rectal suppositories below 25°C (77°F). May be refrigerated

• Mesalamine rectal suppositories may be refrigerated.

• Keep mesalamine rectal suppositories away from direct heat, light, or humidity.

• Keep mesalamine rectal suppositories and all medicines out of the reach of children.

General information about mesalamine rectal suppositories

Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. Do not use mesalamine for a condition for which it was not prescribed. Do not give mesalamine rectal suppositories to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about mesalamine rectal suppositories. For more information, call Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-MYLAN). 

What are the ingredients in mesalamine rectal suppositories?

Active ingredients: Mesalamine, USP

Inactive ingredients: Hypromellose; Carbomer; D&C Red No. 28; and FD&C Blue No. 1. 

This information should not be used for the diagnosis and treatment of any condition. Always consult your doctor or pharmacist before using any mesalamine suppositories. This information is intended for the patient’s personal non-commercial use. This information should not be used to diagnose, treat or prevent any disease. This website is not intended for, and should not be used by, patients or consumer healthcare professionals for the diagnosis, treatment or management of disease.

© 2015 Mylan Pharmaceuticals Inc. All rights reserved.

Manufactured by Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A.

This information has been approved by the U.S. Food and Drug Administration.