

PART III: CONSUMER INFORMATION**MEZAVANT^{®*}****mesalamine Delayed- and Extended-Release Tablets**

This leaflet is part III of a three-part "Product Monograph" published when MEZAVANT was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MEZAVANT. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATIONWhat the medication is used for:

MEZAVANT tablets contain mesalamine, which is an anti-inflammatory drug for the treatment of ulcerative colitis and/or to help maintain remission (mucosal healing) in patients with ulcerative colitis. Ulcerative colitis is a disease of the large bowel (colon) and back passage (rectum), where the lining of the gut becomes red and swollen (inflamed) resulting in symptoms of frequent and bloody stools together with stomach cramps.

What it does:

It is believed that MEZAVANT blocks the production and action of certain substances (cyclooxygenase, prostaglandins and others) involved in producing inflammation. MEZAVANT acts throughout the colon and rectum to treat this inflammation and reduces symptoms, such as bloody stools and diarrhea.

When it should not be used:

- If you are allergic to this drug or its ingredients or components of the container (see What the nonmedicinal ingredients are)
- If you are allergic to a family of drugs known as salicylates [which includes acetylsalicylic acid (i.e., Aspirin[†])].

What the medicinal ingredient is:

mesalamine

What the important nonmedicinal ingredients are:

carnauba wax, magnesium stearate, metacrylic acid copolymer types A and B, red ferric oxide (E172), polyethylene glycol (macrogol) 6000, silica (colloidal hydrated), sodium carboxymethylcellulose, sodium starch glycolate (type A), stearic acid, talc, titanium dioxide (E171) and triethylcitrate

MEZAVANT tablets do not contain gluten or lactose.

What dosage forms it comes in:

1200mg (1.2g) delayed and extended-release tablets

WARNINGS AND PRECAUTIONS

BEFORE you use MEZAVANT, talk to your doctor or pharmacist if:

- You have a narrowing or blockage of the upper digestive tube (e.g., pyloric stenosis).
- You have any kidney or liver problems.
- You have digestive (peptic) ulcers.
- You have had previously inflammation of the heart (which may be the results of an infection of the heart).
- Since mesalamine crosses the placenta in pregnancy and is excreted in breast milk in small quantities, due care should be taken if using MEZAVANT in pregnancy or while breast-feeding. If you are pregnant, think you might be pregnant or are breast-feeding you should ask your doctor for advice about taking MEZAVANT.
- You have had previous allergy (hypersensitivity reaction) to sulfasalazine (an ingredient in other medicines used to treat ulcerative colitis).
- You have had any allergies to this drug or its ingredients or components of the container.

INTERACTIONS WITH THIS MEDICATION

The concomitant use of mesalamine with drugs known to affect the kidney, including some anti-inflammatory drugs (NSAIDs) and azathioprine may increase the risk of renal (kidney) reactions.

In patients receiving azathioprine or 6-mercaptopurine, concurrent use of mesalamine can increase the possibility of having abnormal blood components.

PROPER USE OF THIS MEDICATIONUsual adult dose:

Always take MEZAVANT as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

MEZAVANT should be taken with food. The tablets should be swallowed whole with liquid and should not be chewed or crushed.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take your tablets then take them as usual the next day. Do not take a double dose to make up for a forgotten tablet.

[†] Aspirin is a registered trade-mark of The Bayer Company, Inc.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, MEZAVANT can cause side effects, although not everybody gets them. The most frequently reported adverse events within clinical studies were inflamed colon, headache, abdominal pain (stomach pain), liver function tests abnormal, loose / frequent stools (diarrhea) and nausea (feeling sick).

Other commonly reported adverse reactions or side effects (>1% to <10%) are: painful or bloated stomach, indigestion, gas, vomiting, weakness, fever, joint pain, muscle pain, back pain, rash, high blood pressure, feeling sleepy or tired.

Other less common side effects (seen in less than 1 in 100 patients) are: reduced number of platelets (a blood clotting cell), exacerbation of ulcerative colitis, dizziness, rectal polyp (a non-cancerous growth in the back passage causing symptoms such as constipation and bleeding), trembling or shaking, ear or throat pain, racing heartbeat, acne, hives, fatigue (feeling extremely tired), swollen face, an inflamed pancreas (associated with pain in upper abdomen and back and feeling sick), hair loss, low blood pressure.

The following side effects have been identified with post-marketing use of MEZAVANT: low white blood cell counts, inflammation of the heart muscle and lining around the heart; inflammation of the liver; kidney problems (such as inflammation and scarring of the kidney); inflammation of lungs due to allergic reaction.

The following additional side effects are associated with other medicines containing mesalamine. These are: low blood cell counts (red blood cells, white blood cells or platelets); neuropathy (abnormal or damaged nerves giving a sensation of numbness and tingling); difficulty in breathing; gall stones; allergic swelling of tongue, lips and around eyes; skin redness.

If any of the side effects become serious or persist, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Blood problems and symptoms such as unexplained bruising, unusual bleeding (for example, nose bleeds), fever, sore throat.		√	
Uncommon	Pancreatitis (inflamed or swollen pancreas) and symptoms such as abdominal pain and feeling sick.		√	
With other similar drugs	Acute Intolerance Syndrome - symptoms include cramping, acute stomach pain, bloody and excessive stools (diarrhea), fever, headache and rash. These symptoms could be a sign of a serious condition which occurs rarely but means your treatment would have to be stopped immediately.		√	
With other similar drugs	Allergic reaction - symptoms include swelling of the mouth, throat, difficulty in breathing and rash.		√	
Rare reports from post-marketing experience	Hepatitis (inflammation of the liver) - symptoms include jaundice (yellowing of the skin and eyes) and flu-like symptoms.		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Rare reports from post-marketing experience	Myocarditis/ Pericarditis (inflammation of the heart muscle and lining around the heart) – symptoms include abnormal heartbeat, chest pain that may resemble a heart attack, fatigue, fever and other signs of infection including headache, muscle aches, sore throat, diarrhea, or rashes, joint pain or swelling, leg swelling, shortness of breath.		√	
Rare reports from post-marketing experience	Kidney problems (such as inflammation and scarring of the kidney) – symptoms include blood in the urine, fever, increased or decreased urine output, mental status changes (drowsiness, confusion, coma), nausea, vomiting, rash, swelling of the body, weight gain (from retaining fluid).		√	
Rare reports from post-marketing experience	Hypersensitivity pneumonitis (inflammation of lungs due to an allergic reaction) – symptoms include fever, cough, chills, and shortness of breath.		√	

This is not a complete list of side effects. For any unexpected effects while taking MEZAVANT, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15°C to 25°C).

Keep out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

More information can be found on the internet at: <http://www.mezavant.ca>

This document plus the full product monograph, prepared for health professionals can be provided by contacting the sponsor, Shire Canada Inc. at: 1-800-268-2772

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