

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 a flare-up 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:

MEZAVANT is believed to block the production and action of certain substances (cyclooxygenase, prostaglandins and others) involved in producing inflammation. MEZAVANT tablets use a technology called MMX^{®**}, designed to delay and deliver effective concentrations of medicine for an extended period of time throughout the colon and rectum to treat the inflammation and reduce 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^{®†})]
- If you have severe liver problems
- If you have severe kidney problems.

What the medicinal ingredient is:

mesalamine

What the nonmedicinal ingredients are:

carnauba wax, magnesium stearate, methacrylic acid – methyl methacrylate copolymer (1:1), methacrylic acid – methyl methacrylate copolymer (1:2), 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, lactose or phthalates.

[†] Aspirin is a registered trade-mark of Bayer Aktiengesellschaft

What dosage forms it comes in:

MEZAVANT 1.2g delayed- and extended-release tablets are available as red-brown, oval-shaped, film-coated tablets marked on one side with "S476".

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 chronic lung disease such as asthma or others.
- You have digestive (peptic) or duodenal ulcers.
- You have urinary tract obstructions.
- You have previously had inflammation of the heart (which may be the results of an infection of the heart).
- You have eczema (dry, itchy rashes on your skin). Your skin may be more sensitive to sunlight when taking MEZAVANT.
- 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. This can help bring your symptoms of ulcerative colitis under control and can also reduce the risk of symptoms reappearing. You should check with your doctor or pharmacist if you are not sure.

The usual daily dose for adults is 2.4g to 4.8g (two to four tablets) taken once a day for a flare-up of ulcerative colitis.

The usual daily dose for adults to help maintain remission (mucosal healing) is 2.4g (two tablets) taken once a day.

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.

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	
Common	Allergic reaction - symptoms include hives, rash, swollen face.			√
Unknown	Other allergic reaction - symptoms include swelling of the mouth, throat, difficulty in breathing and worsening asthma.			√
Common	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.		√	

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, back pain, allergic reactions (including hives, rash and swollen face), 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, fatigue (feeling extremely tired), 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), nephrogenic diabetes insipidus (which include passing water (urine) more often than normal and possibly at night (bed wetting), increased thirst, tiredness, loss of appetite and weight loss), inflammation of lungs due to allergic reaction, muscle pain, chest pain, allergic swelling of skin or body parts, increased pressure in brain, Lupus-Like Syndrome (which may include butterfly shaped skin rash typically on face, skin sensitivity to sunlight along with joint pain and/or arthritis), increased sensitivity to sunlight and a reversible decrease in sperm production.

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.

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.		√	
Rare	Kidney problems (such as inflammation and scarring of the kidney or kidney failure) – 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)		√	
Unknown frequency	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	
Unknown frequency	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.		√	
Unknown frequency	Hypersensitivity pneumonitis (inflammation of lungs due to an allergic reaction) – symptoms include fever, cough, chills, and shortness of breath.			√

<p>Unknown frequency</p>	<p>Serious Skin Conditions (Stevens-Johnson syndrome, Drug Reaction with Eosinophilia and Systemic Symptoms) : Swelling of the skin or serious skin rash seen as severe blisters of the skin and mucous membranes</p>			<p>√</p>
<p>Unknown frequency</p>	<p>Increased pressure in brain causing headache which may originate behind your eyes and worsen with eye movements, with blurred or dimmed vision, double vision, seeing light flashes, difficulty seeing to the side, and brief or permanent vision loss. These may be associated with dizziness, nausea, vomiting, ringing in ears.</p>			<p>√</p>

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 associated 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 1908C
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

If you want more information about MEZAVANT:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website <http://hc-sc.gc.ca>, the manufacturer's website www.shirecanada.com, or by calling 1-800-268-2772.

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