

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **MEZERA**®

Mesalazine Suppositories, Mfr. Std.

Read this carefully before you start taking **MEZERA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MEZERA**.

What is MEZERA used for?

- Treatment of active mild to moderate ulcerative proctitis. Ulcerative proctitis is a condition where your rectum becomes inflamed and develops sores or ulcers.

How does MEZERA work?

MEZERA is believed to work by interfering with certain chemicals in your body that cause inflammation (e.g., prostaglandins). This will help reduce the inflammation (swelling and pain) in the rectum and lower part of the large bowel.

What are the ingredients in MEZERA?

Medicinal ingredient: Mesalazine, also known as 5-aminosalicylic acid, 5-ASA or mesalamine.

Non-medicinal ingredient: Hard fat (Witepsol H-12). MEZERA products are gluten-free and phthalate-free.

MEZERA comes in the following dosage forms:

Suppositories of 1 g

Do not use MEZERA if you:

- have severe kidney disease.
- have severe liver disease.
- have ulcers of the stomach or small intestine.
- have a blockage along the urinary tract.
- are allergic to this drug or to any ingredient of MEZERA. See “What are the ingredients in MEZERA?”, above.
- are allergic to salicylates such as Aspirin®.
- are under 2 years old.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MEZERA. Talk about any health conditions or problems you may have, including if you:

- have any kidney or liver problems.
- have lung or breathing problems such as asthma.
- have had previous inflammation of the heart. Talk to your doctor if you suspect that you are experiencing problems with your heart. See “Serious side effects and what to do about them” table, below.
- have a history of allergy to sulfasalazine.
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

Other warnings you should know about:

Urine discoloration: You may notice red-brown urine discoloration after using toilets treated with bleach products. This is because of a chemical reaction between mesalazine and bleach and is harmless.

Monitoring and Testing: During treatment your doctor may want to keep you under close medical supervision and you may need to have regular blood and urine tests.

Kidney Stones: Kidney stones may develop with use of mesalazine. Symptoms may include blood in urine, urinating more often and pain in your back, side, belly or groin. Be sure to drink enough liquids while you are taking MEZERA. Talk to your doctor about how much water or other liquids you should be drinking.

Serious Skin Reactions: Serious skin reactions including drug reaction with eosinophilia and systemic symptoms, Stevens-Johnson syndrome, toxic epidermal necrolysis have been reported in association with mesalazine treatment. Stop using mesalazine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in “Serious side effects and what to do about them” table.

Pregnancy and Breastfeeding: If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your doctor.

- Avoid becoming pregnant while you are taking MEZERA. It may harm your unborn baby.
- Tell your doctor right away if you become pregnant or think you are pregnant during treatment with MEZERA.
- Taking MEZERA during pregnancy have been reported to cause
 - Early labor
 - Birth defects in babies. The baby may develop kidney and heart issues.
- MEZERA is passed into human breastmilk. Talk to your doctor about how to feed your baby.
- If you breastfeed your baby while taking MEZERA, your baby could develop / start to have diarrhea. It is important to monitor your baby’s stool and contact your doctor right away if they have diarrhea. Your doctor may advise you to stop breastfeeding your baby.

Sun Sensitivity: If you have conditions such as atopic dermatitis or eczema, you may be more sensitive to the sun while taking MEZERA. Your doctor may tell you to avoid sun exposure, wear protective clothing, or use a sunscreen while outdoors.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with MEZERA:

- Medicine used to prevent organ transplant rejection called azathioprine
- Medicines used to treat cancer such as 6-mercaptopurine, thioguanine and methotrexate
- Medicine used to treat ulcerative colitis such as aminosalicylates (including MEZERA)
- Medicine used to treat blood clots called warfarin
- Medicines used to treat gout such as probenecid and sulfinpyrazone
- Medicines used to treat high blood pressure such as spironolactone and furosemide
- Medicine used to treat bacterial infections called rifampicin
- Medicine used to treat inflammation called corticosteroids, for example prednisone
- Vaccine against chickenpox (varicella vaccine)

The use of mesalazine with drugs known to affect the kidney may increase the risk of kidney reactions. These drugs include some anti-inflammatory drugs (NSAIDs) and azathioprine.

How to take MEZERA:

Treatment is usually continued for at least 6 weeks.

Not to be taken by mouth.

If possible, go to the toilet and empty your bowels before.

1. Detach one suppository from the strip.
2. Remove the plastic wrapper.
3. Do not handle the suppository too much as it melts at body heat.
4. Insert gently and fully into the rectum, pointed end first.
5. May be easier to insert with a small amount of lube gel on the tip.

Usual dose:

You should use MEZERA suppositories regularly and consistently to achieve the desired effect.

1 suppository (1 g) is inserted into the rectum, once daily at bedtime. For maximum benefit, try to keep the suppository in the rectum for at least one to three hours.

Overdose:

If you think you, or a person you are caring for, have taken too much MEZERA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of MEZERA, use it as soon as possible, unless it is almost time for the next dose. Do not use two doses of MEZERA at the same time to make up for a missed dose.

What are possible side effects from using MEZERA?

These are not all the possible side effects you may have when taking MEZERA. If you experience any side effects not listed here, tell your healthcare professional.

The most commonly reported side effects are: abdominal pain, an abnormal sense of touch, diarrhoea,

constipation, or flatulence (gas).

Other side effects reported with MEZERA include: disturbed vision, burning, pain or discomfort around the anus, bloating, dizziness, headache, hair loss, muscle or joint pain, lowered sperm count (reversible when MEZERA is discontinued), numbness in hands and feet, decreased platelet count in the blood, allergic and fibrotic lung reactions (including difficulty breathing, cough, bronchospasm (lung contraction), alveolitis (alveoli inflammation), pulmonary eosinophilia (lung inflammation from an increase of a type of white blood cells, eosinophils), lung infiltration, pneumonitis (lung inflammation)) and increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Skin Reactions: rash, itching		✓	
UNCOMMON			
Kidney stones (hard little pebbles that form in your kidneys): blood in urine, urinating more often and pain in your back, side, belly or groin.		✓	
RARE			
Myocarditis/ Pericarditis (inflammation of the heart muscle and lining around the heart): 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.		✓	
VERY RARE		✓	
Acute Intolerance Syndrome: cramping, acute stomach pain, blood 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.		✓	
Pancreatitis (inflamed or swollen pancreas): abdominal pain and feeling sick.		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Serious skin reactions including drug reactions with eosinophilia and systemic symptoms, Stevens-Johnson syndrome, toxic epidermal necrolysis: reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, widespread rash, fever and enlarged nodes. These serious skin rashes can be preceded by fever and flu-like symptoms.			✓
Blood problems: unexplained bruising, unusual bleeding (for example, nose bleeds), anemia (feeling weak), fever, sore throat.		✓	
Kidney problems (such as inflammation and scarring of the kidney or kidney failure): 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).		✓	
Hepatitis including liver failure (inflammation of the liver): jaundice (yellowing of the skin and eyes) and flu-like symptoms.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of reach and sight of children.

MEZERA suppositories must be stored between 15 and 30°C. Keep away from direct heat, light and humidity.

If you want more information about MEZERA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.avirpharma.com), or by calling 1-888-430-0436.

This leaflet was prepared by:

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PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **MEZERA**®

Mesalazine Foam Enema, Mfr. Std.

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What is MEZERA used for?

- Treatment of mildly active ulcerative colitis. Ulcerative colitis is a condition where your colon (bowel) and rectum become inflamed and develop sores or ulcers.

How does MEZERA work?

MEZERA is believed to work by interfering with certain chemicals in your body that cause inflammation (e.g., prostaglandins). This will help reduce the inflammation (swelling and pain) in the rectum and lower part of the large bowel.

What are the ingredients in MEZERA?

Medicinal ingredient: Mesalazine, also known as 5-aminosalicylic acid, 5-ASA or mesalamine.

Non-medicinal ingredients: cetostearyl alcohol, disodium edetate, polysorbate 60, propylene glycol, sodium metabisulfite, with a propellant mixture of propane, n-butane, and isobutane. MEZERA products are gluten-free and phthalate-free.

MEZERA comes in the following dosage forms:

Foam enema of 1 g / actuation

Do not use MEZERA if you:

- have severe kidney disease.
- have severe liver disease.
- have ulcers of the stomach or small intestine.
- have a blockage along the urinary tract.
- are allergic to this drug or to any ingredient of MEZERA. See “What are the ingredients in MEZERA?”, above.
- are allergic to salicylates such as Aspirin®.
- are under 2 years old.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MEZERA. Talk about any health conditions or problems you may have, including if you:

- have any kidney or liver problems.
- have lung or breathing problems such as asthma.

- have had previous inflammation of the heart. Talk to your doctor if you suspect that you are experiencing problems with your heart. See “Serious side effects and what to do about them” table, below.
- have a history of allergy to sulfasalazine.
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

Other warnings you should know about:

MEZERA foam enema contains propylene glycol, sodium metabisulphite and cetostearyl alcohol, which may cause:

- A buildup of acidity in the blood (Lactic acidosis), with symptoms of muscle aches, rapid breathing, nausea and stomach pain.
- Blood sugar issues (hyperosmolality) with symptoms of excessive thirst, dry mouth, increased urination, fever, drowsiness, confusion and hallucinations.
- Blood issues (hemolysis) with symptoms of pale skin, fatigue, weakness, fever, signs of confusion, dizziness, or light-headedness.
- Central Nervous System (CNS) depression, with symptoms of decrease heartrate, decreased rate of breathing and loss of consciousness.
- Severe hypersensitivity reactions.
- Bronchospasm.
- Skin reactions.

Stop taking MEZERA and talk to your doctor if you experience any of these issues during your treatment.

Urine discoloration: You may notice red-brown urine discoloration after using toilets treated with bleach products. This is because of a chemical reaction between mesalazine and bleach and is harmless.

Monitoring and Testing: During treatment your doctor may want to keep you under close medical supervision and you may need to have regular blood and urine tests.

Kidney Stones: Kidney stones may develop with use of mesalazine. Symptoms may include blood in urine, urinating more often and pain in your back, side, belly or groin. Be sure to drink enough liquids while you are taking MEZERA. Talk to your doctor about how much water or other liquids you should be drinking.

Serious Skin Reactions: Serious skin reactions including drug reaction with eosinophilia and systemic symptoms, Stevens-Johnson syndrome, toxic epidermal necrolysis have been reported in association with mesalazine treatment. Stop using mesalazine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in “Serious side effects and what to do about them” table.

Pregnancy and Breastfeeding: If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your doctor.

- Avoid becoming pregnant while you are taking MEZERA. It may harm your unborn baby.
- Tell your doctor right away if you become pregnant or think you are pregnant during treatment with MEZERA.

- Taking MEZERA during pregnancy have been reported to cause
 - Early labor
 - Birth defects in babies. The baby may develop kidney and heart issues.
- MEZERA is passed into human breastmilk. Talk to your doctor about how to feed your baby.
- If you breastfeed your baby while taking MEZERA, your baby could develop / start to have diarrhea. It is important to monitor your baby's stool and contact your doctor right away if they have diarrhea. Your doctor may advise you to stop breastfeeding your baby.

Sun Sensitivity: If you have conditions such as atopic dermatitis or eczema, you may be more sensitive to the sun while taking MEZERA. Your doctor may tell you to avoid sun exposure, wear protective clothing, or use a sunscreen while outdoors.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with MEZERA:

- Medicine used to prevent organ transplant rejection called azathioprine
- Medicines used to treat cancer such as 6-mercaptopurine, thioguanine and methotrexate
- Medicine used to treat ulcerative colitis such as aminosalicylates (including MEZERA)
- Medicine used to treat blood clots called warfarin
- Medicines used to treat gout such as probenecid and sulfinpyrazone
- Medicines used to treat high blood pressure such as spironolactone and furosemide
- Medicine used to treat bacterial infections called rifampicin
- Medicine used to treat inflammation called corticosteroids, for example prednisone
- Vaccine against chickenpox (varicella vaccine)

The use of mesalazine with drugs known to affect the kidney may increase the risk of kidney reactions. These drugs include some anti-inflammatory drugs (NSAIDs) and azathioprine.

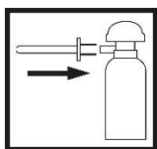
How to take MEZERA:

Treatment is usually continued for at least 6 weeks.

If possible, go to the toilet and empty your bowels before.

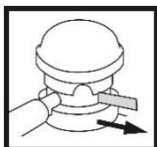
Prepare to use the foam:

Figure 1



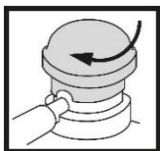
1. Store and use MEZERA foam enema at room temperature (15 - 30°C).
2. Push the applicator firmly onto the spout of the spray can (Figure 1).
3. Shake the spray can for 20 seconds.

Figure 2



4. Remove the safety tab from under the pump dome (Figure 2).

Figure 3



5. Twist the dome on the top of the spray can until the semi-circular gap is in line with the nozzle (Figure 3). The spray can is now ready for use.

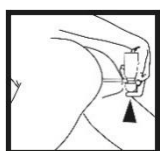
Use the foam:

Figure 4



6. Place your index finger on the top of pump dome. Turn the can upside down (Figure 4). The spray can will only work when held with the pump dome pointing down.

Figure 5



7. Insert the applicator into your rectum as far as possible (Figure 5). The best way to do this is to place one foot on a chair or stool.
8. Push down the pump dome fully once. Slowly release it.
9. Wait 10-15 seconds for the foam to be delivered. For the second spray, push the dome again and release slowly. Wait a further 10-15 seconds.

Figure 6



10. Remove the applicator and dispose of it in the plastic bag provided (Figure 6). Take a new one for each use.
11. Wash your hands and try not to empty your bowels until the next morning.

Usual dose:

You should use MEZERA foam enema regularly and consistently to achieve the desired effect.

2 spray actuations (1 g/spray) once daily at bedtime. If you have difficulty retaining this amount of foam, it may also be used in two separate doses: one at bedtime and the other during the night or early in the morning (after excreting the first dose). The foam is provided with 14 single-use applicators. Each canister contains enough foam for 14 spray actuations, which corresponds to 7 days of treatment. The applicators can be used to track your treatment (number of dose used/remaining).

Overdose:

If you think you, or a person you are caring for, have taken too much MEZERA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of MEZERA, use it as soon as possible, unless it is almost time for the next dose. Do not use two doses of MEZERA at the same time to make up for a missed dose.

What are possible side effects from using MEZERA?

These are not all the possible side effects you may have when taking MEZERA. If you experience any side effects not listed here, tell your healthcare professional.

The most commonly reported side effects are: abdominal pain, an abnormal sense of touch, diarrhoea, constipation, or flatulence (gas).

Other side effects reported with MEZERA include: disturbed vision, burning, pain or discomfort around the anus, bloating, dizziness, headache, hair loss, muscle or joint pain, lowered sperm count (reversible when MEZERA is discontinued), numbness in hands and feet, decreased platelet count in the blood, allergic and fibrotic lung reactions (including difficulty breathing, cough, bronchospasm (lung contraction), alveolitis (alveoli inflammation), pulmonary eosinophilia (lung inflammation from an increase of a type of white blood cells, eosinophils), lung infiltration, pneumonitis (lung inflammation)) and increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Skin reactions: rash, itching		✓	
UNCOMMON			
Kidney stones (hard little pebbles that form in your kidneys): blood in urine, urinating more often and pain in your back, side, belly or groin.		✓	
RARE			
Myocarditis/ Pericarditis (inflammation of the heart muscle and lining around the heart): 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.		✓	
VERY RARE			
Acute Intolerance Syndrome: cramping, acute stomach pain, blood and excessive stools (diarrhea), fever, headache and rash. These symptoms could be a sign of a serious condition which occurs rarely but means your		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
treatment would have to be stopped immediately.			
Pancreatitis (inflamed or swollen pancreas): abdominal pain and feeling sick.		✓	
Serious skin reactions including drug reactions with eosinophilia and systemic symptoms, Stevens-Johnson syndrome, toxic epidermal necrolysis: reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, widespread rash, fever and enlarged nodes. These serious skin rashes can be preceded by fever and flu-like symptoms.			✓
Blood problems: unexplained bruising, unusual bleeding (for example, nose bleeds), anemia (feeling weak), fever, sore throat.		✓	
Kidney problems (such as inflammation and scarring of the kidney or kidney failure): 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).		✓	
Hepatitis including liver failure (inflammation of the liver): jaundice (yellowing of the skin and eyes) and flu-like symptoms.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of reach and sight of children.

MEZERA foam enema should be stored between 15 to 30°C. Contents under pressure. Do not place in hot water or near radiators, stoves or other sources of heat. Do not puncture or incinerate container or store at temperatures over 50°C. Do not refrigerate or freeze. Discard 12 weeks after first use.

If you want more information about MEZERA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.avirpharma.com), or by calling 1-888-430-0436.

This leaflet was prepared by:

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