

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrMETRONIDAZOLE INJECTION USP

Read this carefully before you receive **METRONIDAZOLE INJECTION USP**. 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 **METRONIDAZOLE INJECTION USP**.

What is METRONIDAZOLE INJECTION USP used for?

METRONIDAZOLE INJECTION USP is used to:

- treat infections of the:
 - stomach area (abdominal cavity)
 - brain
 - lung
- prevent infections after colon and/or rectum surgery.

Antibacterial drugs like METRONIDAZOLE INJECTION USP treat **only** bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, METRONIDAZOLE INJECTION USP should be used exactly as directed. Misuse or overuse of METRONIDAZOLE INJECTION USP could lead to the growth of bacteria that will not be killed by METRONIDAZOLE INJECTION USP (resistance). This means that METRONIDAZOLE INJECTION USP may not work for you in the future. Do not share your medicine.

How does METRONIDAZOLE INJECTION USP work?

METRONIDAZOLE INJECTION USP belongs to a class of medicines called antibacterials. It kills the bacteria that cause the infection.

What are the ingredients in METRONIDAZOLE INJECTION USP?

Medicinal ingredients: Metronidazole

Non-medicinal ingredients: Citric Acid, Sodium Chloride, Dibasic Sodium Phosphate and Water for Injection

METRONIDAZOLE INJECTION USP comes in the following dosage forms:

Solution: 5 mg/mL

Do not use METRONIDAZOLE INJECTION USP if:

- you are allergic (hypersensitive) to:
 - metronidazole
 - other medicines like metronidazole (called nitroimidazole derivatives)
 - to any of the nonmedicinal ingredients in the formulation (see “What are the ingredients in METRONIDAZOLE INJECTION USP”) or components of the flexible container (PVC)
- you have:

- a genetic disorder called Cockayne Syndrome. Severe liver damage that may be fatal has happened when people with Cockayne syndrome have taken metronidazole.
- a disease of the nervous system
- a history of blood-disorders
- a condition where your thyroid does not produce enough hormones (hypothyroidism)
- a condition (hypoadrenalism) where your body does not produce enough of certain hormone (cortisol and aldosterone)

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

- have other infections
- drink alcohol
- are taking disulfiram (a medicine used to treat alcoholism) or have taken disulfiram within the last 2 weeks
- have kidney problems
- have liver problems
- have an active or chronic severe disease of the nervous system
- have any blood disorder (e.g., transient eosinophilia, leukopenia or other)
- have a history of edema (swelling of the legs, ankles and/or feet)
- you are on a low sodium diet or taking corticosteroids (medicines used to provide relief for swollen areas of the body)
- are pregnant or plan to get pregnant
- are breastfeeding, or plan to breastfeed. Metronidazole passes in the mother's milk and may affect your baby. You and your healthcare professional will decide whether you should take metronidazole while breastfeeding.

Other warnings you should know about:

Driving and using machines: After you received metronidazole, you may feel dizzy, confused, have fits (seizures) or temporary eyesight problems (such as blurred or double vision). Before driving a vehicle or using machinery wait to see how you feel after receiving METRONIDAZOLE INJECTION USP.

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 METRONIDAZOLE INJECTION USP:

- Alcohol
- Disulfiram, a medicine used to treat alcoholism
- Warfarin (Coumadin), a medicine used to prevent blood clot
- Phenobarbital, Phenytoin (Dilantin), carbamazepine, medicines used to treat seizures (epilepsy)
- Vecuronium, a medicine used to relax the muscles

- Lithium, a medicine used to treat mood disorders
- Busulfan (Myleran®), a medicine used to treat certain blood cancer
- Cimetidine, a medicine used to relieve certain stomach problems
- Amiodarone, quinidine, medicines used to treat irregular heartbeats
- Cyclosporine, tacrolimus, medicines used to prevent organ rejection after a transplant
- 5-Fluorouracil, used to treat cancer
- Medications that may cause heart rhythm changes (QT prolongation), like certain antiarrhythmics (medicines for heart rhythm disorders), certain antibiotics, and mental health medicines

If you are not sure, talk to your healthcare professional before using metronidazole.

How METRONIDAZOLE INJECTION USP is given:

- Your healthcare professional will inject metronidazole slowly into your vein (intravenous infusion)
- Do NOT drink alcohol before, during, and up to 72 hours after receiving METRONIDAZOLE INJECTION USP. Avoiding alcohol will help prevent side effects such as stomach pain, nausea, vomiting, very fast or uneven heartbeat (palpitations), headaches and flushing.

Usual Dose:

Your healthcare professional will decide the right dose of metronidazole for you.

Overdose:

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

Missed Dose:

If you miss your scheduled dose, contact your healthcare professional as soon as possible to schedule your next treatment.

What are possible side effects from using METRONIDAZOLE INJECTION USP?

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

Side effects may include:

- constipation
- indigestion (upset stomach)
- loss of appetite
- stomach pain
- diarrhea
- nausea, vomiting

- dry mouth
- swelling or change in colour of the tongue (furry tongue)
- unpleasant metallic taste
- dark urine
- painful urination
- flushing
- headaches
- trouble sleeping, feeling tired
- itching, hives, rash

METRONIDAZOLE INJECTION USP can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

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	
Allergic Reaction: difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives, or rash, swelling of the face, lips, tongue or throat			√
Heart Problems: very fast or uneven heartbeat, chest pain, dizziness, weakness, blurred vision, fainting. This may also happen when METRONIDAZOLE INJECTION USP is taken with drugs that can cause QT prolongation (a heart rhythm condition)			√
Depression: (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive) and thoughts of death or suicide.		√	
Optic neuropathy: (swelling in the eye that damages the optic nerve):		√	

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	
pain when moving the eye, blurred vision, vision loss			
Pancreatitis: (inflammation of the pancreas) upper abdominal pain, fever, rapid heartbeat, nausea, vomiting, tenderness when touching the abdomen			√
Jaundice: yellowing of the skin and eyes, dark urine, light coloured stool, itching all over your body		√	
Encephalopathy (problem in the brain): Symptoms may include change in mental state, with problems such as: confusion, difficulty thinking, disorientation, passing out, hallucinations, sudden involuntary muscle jerks, shaking or twitches			√
Ataxia: inability to coordinate voluntary movements, problems using your arms and legs			√
Peripheral neuropathy: Numbness, burning, tingling, pain in the hands and/or feet, sensitivity to touch		√	
Dysarthria (difficulty speaking)		√	
Seizures (fit): uncontrollable shaking with or without loss of consciousness			√
Meningitis: fever, nausea, vomiting, headache, stiff neck, extreme sensitivity to bright light, confusion, seizures, sleepiness or difficulty waking, no appetite or thirst, skin rash			√
Stevens-Johnson syndrome (SJS) (severe skin rash): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills,			√

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	
headache, cough, body aches or swollen glands.			
Toxic Epidermal Necrolysis (TEN) (severe skin reaction): redness, blistering and/or peeling of large areas of the body			√
Drug reaction with eosinophilia and systemic symptoms (DRESS) (serious skin reaction that may affect more than one or more organs): fever, severe rash, peeling skin, swollen lymph glands, flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feel thirsty, urinating less often, less urine			√
Vaginal Yeast Infection: vaginal dryness, burning and discharge		√	
Muscular Disorders: Muscle spasms, muscle aches and pain, joint stiffness		√	
Thrombophlebitis (blood clot in the vein of the leg or arm): swelling and redness along the vein which is extremely tender or painful when you touch the area		√	
General feeling of discomfort (malaise), face swelling, swelling of your lower legs or hands (edema peripheral), chills, pain, burning or swelling at the injection site		√	
Leukopenia / Neutropenia (decreased white blood cells): infections, fatigue, fever, aches, pains and flu-like symptoms		√	
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness		√	

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:

Store at room temperature (20°C to 25°C), and protect from light and freezing.

Keep out of reach and sight of children.

If you want more information about METRONIDAZOLE INJECTION USP:

- 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 <https://www.pfizer.ca/>, or by calling 1-800-463-6001.

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