

PART III: CONSUMER INFORMATION

**^{Pr}Metronidazole Injection USP
(Metronidazole)
Solution, 5 mg/mL**

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

ABOUT THIS MEDICATION

What the medication is used for:

Metronidazole Injection USP is used to:

- Treat infections of the abdominal cavity, brain, or lung.
- Prevent infections in patients having colorectal 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.

What it does:

Metronidazole Injection USP kills the bacteria that cause the infection.

When it should not be used:

Do not use Metronidazole Injection USP and tell your doctor if you:

- are allergic (hypersensitive) to metronidazole
- are allergic (hypersensitive) to any of the nonmedicinal ingredients in the formulation (see "What the nonmedicinal ingredients are") or components of the flexible container (PVC)
- have a disease of the nervous system
- have a history of blood-disorders, hypothyroidism (underactive thyroid gland) or hypoadrenalism (underactive adrenal gland)

What the medicinal ingredient is:

Metronidazole

What the nonmedicinal ingredients are:

Citric Acid
Sodium Chloride
Dibasic Sodium Phosphate
Water for Injection

What dosage forms it comes in:

5 mg/mL sterile, solution

WARNINGS AND PRECAUTIONS

BEFORE receiving Metronidazole Injection USP talk to your doctor, pharmacist, or nurse if you:

- have other infections
- have Cockayne Syndrome
- have been consuming alcohol
- 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)
- are pregnant or plan to get pregnant
- are breastfeeding, or plan to breastfeed, as metronidazole is excreted in human breast milk
- are less than 18 years of age

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with Metronidazole Injection USP:

- Disulfram
- Medicines used to thin the blood such as warfarin (Coumadin)
- Phenobarbital or Phenytoin (Dilantin)
- Vecuronium
- Lithium
- Busulfan (Myleran®)
- 5-Fluorouracil

If you are not sure, talk to your doctor or pharmacist before using metronidazole.

Do not drink any alcohol while you are receiving Metronidazole Injection USP. Consumption of alcohol with metronidazole may cause headaches and flushing.

PROPER USE OF THIS MEDICATION

Usual adult dose:

The appropriate dose is selected by the Health Care Professional and is administered through a vein.

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 miss your scheduled infusion, contact your doctor or nurse as soon as possible to schedule your next treatment.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- Nausea, diarrhea, vomiting, constipation
- Indigestion, loss of appetite
- abdominal pain
- dry mouth, furred tongue
- unpleasant metallic taste
- dark urine
- painful urination
- flushing
- headaches
- trouble sleeping, feeling tired
- skin rash and itching

Metronidazole Injection USP can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

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

Symptom / effect	Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Allergic Reaction: rash, blisters, mouth sores, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, fever.			√
Cardiac Disorders: Chest pain, unusually rapid, strong, or irregular heartbeat, difficulty breathing (Dyspnea)		√	
Eye disorders: blurred vision, vision loss		√	
Gastrointestinal disorders: Pancreatitis (inflammation of the pancreas) with symptoms such as severe abdominal pain which may reach through to your back, especially associated with nausea, vomiting and		√	

fatigue. Stomach pain, diarrhea which can be bloody, fever			
Nervous System Disorders: inability to coordinate voluntary movements, problems using your arms and legs, feel confused, seizures, stiff neck associated with headache, dizziness, drowsiness and insomnia			√
Skin Disorders: Numbness, burning, tingling, pain in the hands and/or feet, sensitivity to touch		√	
Vaginal Yeast Infection: vaginal dryness, burning and discharge		√	
Muscular Disorders: Muscle spasms		√	
General Disorders and Administration Site Conditions: Injection site reaction, Malaise, Face edema, Edema peripheral, Chills, Pain, burning or swelling at the injection site.			√

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

HOW TO STORE IT

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

Keep out of reach and sight of children.

Reporting Suspected 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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Pfizer Canada Inc., at 1-800-463-6001.

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