

PART III: CONSUMER INFORMATION

Pr Meropenem for Injection SDZ
Meropenem for Injection, USP
meropenem (as meropenem trihydrate)

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

ABOUT THIS MEDICATION**What the medication is used for:**

Meropenem for Injection SDZ is used to treat bacterial infections which may occur in the lungs, bladder and kidneys, abdomen, skin, brain (meningitis), female reproductive organs (including infections which may occur after child birth) and infections of the blood which may include the whole body.

Antibacterial drugs like Meropenem for Injection treat only bacterial infections. They do not treat viral infections. Although you may feel better early in treatment, Meropenem for Injection should be used exactly as directed. Misuse or overuse of Meropenem for Injection could lead to the growth of bacteria that will not be killed by Meropenem for Injection (resistance). This means that Meropenem for Injection may not work for you in the future.

What it does:

Meropenem for Injection SDZ prevents the formation of the bacterial cell wall, leading to bacterial death and a reduction in the infection.

When it should not be used:

If you are allergic to meropenem or any of the other ingredients of Meropenem for Injection SDZ..

What the medicinal ingredient is:

Meropenem (as meropenem trihydrate)

What the nonmedicinal ingredients are:

Sodium carbonate

What dosage forms it comes in:

Meropenem for Injection SDZ is available as an injection for intravenous use (into a large vein) containing either 500 mg or 1 g of meropenem.

Meropenem for Injection SDZ 500 mg is supplied in 20 mL injection vial.

Meropenem for Injection SDZ 1 g is supplied in 30 mL injection vial.

WARNINGS AND PRECAUTIONS

BEFORE you use, Meropenem for Injection SDZ talk to your doctor or pharmacist if you:

- have ever had an allergic reaction to any other antibiotic including penicillins, carbapenems or other cephalosporins;
- are taking carbapenems or valproic acid;
- have any health problems in particular if you have any problems with your kidneys;
- have suffered diarrhoea as a result of taking other antibiotics;
- are pregnant or trying to become pregnant;
- are breast-feeding or planning to breastfeed.

While being treated with Meropenem for Injection SDZ:

- tell your doctor immediately if you develop a severe skin rash or blisters.

- Your injection must not be mixed with or added to solutions containing other drugs.
- Meropenem for Injection SDZ is not recommended for children under 3 months of age.
- Meropenem for Injection SDZ should only be given to the patients for whom it has been prescribed.
- You should only stop receiving Meropenem for Injection SDZ when your doctor tells you.

Driving and using machines

Meropenem for Injection SDZ has been associated with adverse effects such as headache and involuntary muscle movements, shaking or convulsions that could result in loss of consciousness. Do not drive or operate machinery if you have these symptoms.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about any other medicines you are taking including probenecid (for gout) or sodium valproate (antiepileptic).

PROPER USE OF THIS MEDICATION**Usual dose:**

Meropenem for Injection SDZ will be given to you by your doctor or a nurse.

Intravenous injection: this will be dissolved in the liquid specified by your doctor and will be given to you intravenously (in the vein) by the healthcare professional.

The exact dose you are given will be decided by your doctor. It will vary depending on the type of infection that you have, where the infection is in the body and the severity of the infection.

Adults

The dose for adults is usually 500 mg to 1 g given every 8 hours. For meningitis (infection of the brain), the dose is 2 grams given every 8 hours.

The dose for children over 3 months old and up to 12 years of age is decided using the weight of the child. The usual dose range is 10 to 40 mg of Meropenem for Injection SDZ for each kilogram of body weight given every 8 hours.

The dose of Meropenem for Injection SDZ may need to be reduced if your kidneys are not working properly.

Your injections should normally be given at the same times each day.

Overdose:

If you are accidentally given more than the prescribed dose you should talk to a doctor or pharmacist immediately.

If you think you have taking too much Meropenem for Injection SDZ, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose

If you feel an injection was missed during treatment, talk to your (attending) healthcare professional.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Meropenem for Injection SDZ can have side effects.

Common side effects include: inflammation at site of injection, nausea, vomiting, diarrhea, skin rash, headache, and tingling

Other side effects include: itchiness, abdominal pain, sore veins where Meropenem for Injection SDZ is injected, fungal infections of the mouth or the vagina, rare allergic reactions and very rarely damage to red blood cells. Signs of this include unexpected breathlessness and/or red/brown urine, and should be reported to your doctor immediately.

Occasionally Meropenem for Injection SDZ may be associated with changes in your blood which may require your doctor to do certain blood tests.

Convulsions have been reported occasionally.

Do not be alarmed by this list of possible events. You may not have any of them.

If you notice any side effects whilst using Meropenem for Injection SDZ please inform your doctor or pharmacist.

If you experience symptoms such as severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness, you may have *Clostridium difficile* colitis (bowel inflammation). If this occurs, stop taking Meropenem for Injection SDZ and contact your healthcare professional immediately.

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	n/a			
Uncommon	Serious hypersensitivity and allergic reactions, occasionally fatal, with symptoms such as severe rash with or without high fever, with itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing		✓	
	Seizures		✓	
	Inflammation of the colon caused by a bacteria, <i>Clostridium</i> (Pseudomembranous colitis)		✓	
	Severe skin reactions like erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever)		✓	
Rare	Delirium		✓	

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
Not Known	Serious hypersensitivity reactions involving fever, skin rash, enlarged lymph nodes, and changes in blood tests (increased liver enzymes and white blood cells)†. These may be signs of a multi-organ sensitivity disorder known as DRESS or of a skin reaction known as AGEP.		✓	

***If you think you have these side effects, it is important that you seek medical advice from your doctor immediately.**

†These would only be seen if a blood test was done.

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

HOW TO STORE IT

The healthcare professional will store, prepare, dispense, administer and dispose of the medication. Before vials are prepared, the medication should be stored at 15°C - 30°C and not frozen.

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 \(https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html\)](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

If you want more information about Meropenem for Injection SDZ:

- 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://www.healthcanada.gc.ca); the manufacturer's website www.sandoz.ca, or by calling 1-800-361-3062

or by written request at:
110 Rue de Lauzon
Boucherville QC
J4B 1E6

Or by e-mail at:
medinfo@sandoz.com

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