PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{Pr} Pentamidine Isetionate for Injection BP

Pentamidine isetionate

Read this carefully before you start taking **Pentamidine Isetionate for Injection BP** 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 **Pentamidine Isetionate for Injection BP**.

Serious Warnings and Precautions

• This medicine may cause serious reactions, sometimes leading to death, including:

- -very low blood pressure, even after 1 dose
- -very low blood sugar
- irregular heartbeat
- inflamed pancreas
- leakage of the medicine outside the vein which can cause:
 - tissue irritation and sores
 - cell death
 - other complications

• Your doctor will only use this product in hospital setting with the facilities to test:

- blood sugar
- blood cell count
- -kidney and liver function
- -heart rate
- Your doctor will consider the following conditions you may have before deciding that this medicine is right for you:
 - high or low blood pressure
 - high or low blood sugar
 - low number of white or red blood cells, platelets
 - -any liver or kidney problem

What is Pentamidine Isetionate for Injection BP used for?

Pentamidine Isetionate for Injection BP is a medicine used to treat infection in the lung (pneumonia).

How does Pentamidine Isetionate for Injection BP work?

Pentamidine isetionate prevents the growth of the microbe and causes its death.

What are the ingredients in Pentamidine Isetionate for Injection BP?

Medicinal ingredients: Pentamidine isetionate.

Non-medicinal ingredients: The formulation does not contain any non-medicinal ingredients.

Pentamidine Isetionate for Injection BP comes in the following dosage forms:

Powder for solution: 300 mg/vial.

Do not use Pentamidine Isetionate for Injection BP if:

• You are hypersensitive to this drug or to any part of the container.

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

- Have liver, pancreas or kidney problems
- Have high or low blood pressure
- Have high or low blood sugar level
- Have low white blood cells (leukopenia)
- Have low red blood cells (anemia)
- Have low blood platelets (thrombocytopenia)
- Have low blood calcium levels (hypocalcemia)
- Have irregular heart rate or rhythm
- Are pregnant or planning to become pregnant
- Are breastfeeding or planning to breastfeed.

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 Pentamidine Isetionate for Injection BP:

- Drugs that are potentially toxic to the kidneys:
 - Aminoglycosides
 - Amphotericin B
 - Cisplatin
 - Methoxyfluorane
 - Vancomycin
- Drugs that are potentially harmful to the liver or blood cells.

How to take Pentamidine Isetionate for Injection BP:

Pentamidine Isetionate for Injection BP will always be prepared and given to you by a doctor or a healthcare professional. You may receive the medicine through a vein in the hand or arm, or injected into a muscle of the upper leg or buttock.

Usual adult dose:

The usual dose is 4 mg/kg once a day for 14 to 21 days, or as decided by your doctor. Your doctor may order blood tests before, during and after treatment.

Overdose:

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

Missed Dose:

If you missed a scheduled dose, contact your doctor for instruction.

What are possible side effects from using Pentamidine Isetionate for Injection BP?

Like all medicines, Pentamidine Isetionate for Injection BP can cause side effects. If any side effects occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

These are not all the possible side effects you may feel when taking Pentamidine Isetionate for Injection BP. If you experience any side effects not listed here, contact your healthcare professional. Please also see the Serious Warnings and Precautions section above.

Common side effects include:

- Local reactions at the site of injection (pain, swelling and accumulation of pus, change in colour or appearance of the skin)
- Low folate blood level
- Low calcium blood (hypocalcemia)
- Low number of red blood cells (anemia)
- Low number of platelets in the blood (thrombocytopenia)
- Abnormal liver blood tests
- Nausea
- Vomiting
- Skin redness (flushing)
- Unpleasant taste
- Rash, itching
- Pain or tenderness at the injection side.

Less common side effects include:

- High level of blood sugar (hyperglycemia)
- High level of blood urea nitrogen and serum creatinine
- High level of potassium in the blood (hyperkalemia)
- High level of albumin in the urine (albuminuria)
- High level of glucose in the urine (glycosuria)

- Red spots on the skin (erythema multiforme)
- Dizziness
- Fainting (or loss of consciousness)
- Hair loss (alopecia)
- Hallucinations
- Blood clot in vein
- Death.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and
	Only if severe	In all cases	get immediate medical help
VERY COMMON			
Kidney problems, less urine, change in the colour of your urine			\checkmark
Low blood pressure			
COMMON			
Low blood sugar levels			
Low white blood cells count (less than 1,000/mm3), low blood platelets count (less than 20,000/mm3)			V
Low calcium levels in the blood serum			\checkmark
RARE			
Acute inflammation of the pancreas			\checkmark
Irregular heart rate or rhythm (a condition called QT interval prolongation and/or torsade de pointes)			N

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 (<u>https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html</u>) 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:

The healthcare professional will store the product according to the professional product information. Keep out of reach and sight of children.

If you want more information about [Pentamidine Isetionate for Injection BP]:

- 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:

 (<u>https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-products/drug-product-database.html</u>; the manufacturer's website <u>https://www.pfizer.ca/</u>, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC

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