

## PENTAMIDINE-EMC

### Pentamidine Isetionate powder for Injection

Pentamidine Isetionate

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about PENTAMIDINE-EMC

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you being given PENTAMIDINE-EMC against the benefits they expect it will have for you.

**If you have any concerns about being given this medicine, ask your doctor or pharmacist.**

**Keep this leaflet in a safe place.**

You may need to read it again.

### What PENTAMIDINE-EMC is used for

PENTAMIDINE-EMC is used to treat an infection called *Pneumocystis carinii* pneumonia (PCP). This kind of pneumonia occurs commonly in patients whose immune system is not working normally, such as cancer patients, transplant patients, or patients with acquired immune deficiency syndrome (AIDS). PENTAMIDINE-EMC can also be used to treat other types of protozoal infections, such as Leishmaniasis and Trypanosomiasis.

Your doctor may have prescribed PENTAMIDINE-EMC for another reason.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

There is no evidence that PENTAMIDINE-EMC is addictive.

This medicine is available only with a doctor's prescription.

### Before you are given PENTAMIDINE-EMC

#### *When you must not be given it*

**You must not be given PENTAMIDINE-EMC if you have an allergy to pentamidine.**

Symptoms of an allergic reaction to pentamidine may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

**You should not be given PENTAMIDINE-EMC if you are pregnant or intend to become pregnant.**

Pentamidine is not recommended for use during pregnancy. If there is a need to consider pentamidine during your pregnancy, your doctor will discuss with you the benefits and risks of being given it.

**You should not be given PENTAMIDINE-EMC if you are breastfeeding or plan to breast-feed.**

Pentamidine is not recommended while you are breast-feeding, as it is not known whether pentamidine passes into breast milk. If there is a need to consider pentamidine while you

are breastfeeding, your doctor will discuss with you the benefits and risks of being given it.

**If you are not sure whether you should be given PENTAMIDINE-EMC, talk to your doctor or pharmacist.**

#### *Before you are given it*

**Tell your doctor or pharmacist if you have allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes.

**Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:**

- malnutrition
- high or low blood sugar levels
- liver problems
- kidney problems
- heart problems
- blood pressure problems (high or low blood pressure)
- low numbers of red blood cells, white blood cells, or platelets.

**If you have not told your doctor or pharmacist about any of the above, tell them before you are given PENTAMIDINE-EMC.**

#### *Taking other medicines*

**Tell your doctor or pharmacist if you are taking/using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and pentamidine may interfere with each other. These include:

- Amphotericin B, a drug used to treat serious fungal infections
- aminoglycoside antibiotics, such as gentamicin
- cisplatin, a drug used to treat certain types of cancer
- vancomycin, a type of antibiotic
- foscarnet, an antiviral drug used to treat cytomegalovirus (CMV) infections in AIDS patients.

These medicines may be affected by pentamidine, or may affect how well it works. You may need different amounts of your medicine, or you may need to take/use different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while being given pentamidine.

### How PENTAMIDINE-EMC is given

#### *How much is given*

Your doctor will decide what dose of pentamidine you will receive. This depends on your condition and other factors, such as your weight.

#### *How it is given*

PENTAMIDINE-EMC is given as a slow injection into a vein (intravenously) over a period of at least 60 minutes. Pentamidine Isetionate for Injection must only be given by a doctor or nurse.

Some patients develop sudden, severe low blood pressure after a dose of pentamidine. Therefore, you should be lying down while you are being given pentamidine. Your blood pressure will be closely monitored.

#### *How long it is given*

To treat *Pneumocystis carinii* pneumonia (PCP), PENTAMIDINE-EMC is usually given once daily for 14 days.

To treat Leishmaniasis, PENTAMIDINE-EMC may be given once, twice or three times a week.

To treat Trypanosomiasis, PENTAMIDINE-EMC may be given either daily or on alternate days for a total of 7 to 10 doses.

#### *If you are given too much (Overdose)*

**As PENTAMIDINE-EMC is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any severe side effects after being given this medicine, tell your doctor immediately, telephone the Poisons Information Centre (telephone 13 11 26) for advice, or go to the Accident and Emergency department at your nearest hospital.**

You may need urgent medical attention.

Symptoms of a pentamidine overdose may include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

### While you are being given PENTAMIDINE-EMC

#### *Things you must do*

**Tell any other doctors, dentists, and pharmacists who are treating you that you are being given pentamidine.**

**If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given pentamidine.**

**If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given pentamidine.**

**If you become pregnant while being given pentamidine, tell your doctor immediately.**

**Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests (such as blood and platelet counts, blood glucose tests or liver function tests) from time to time to make sure the medicine is working and to prevent unwanted side effects.

#### *Things to be careful of*

**Be careful driving or operating machinery until you know how PENTAMIDINE-EMC affects you.**

Pentamidine may cause dizziness and light-headedness in some people.

Make sure you know how you react to pentamidine before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

If you drink alcohol, dizziness or light-headedness may be worse.

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## Side effects

**Tell your doctor or nurse as soon as possible if you do not feel well while you are being given PENTAMIDINE-EMC.**

This medicine helps most people with protozoal infections, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

**Ask your doctor, pharmacist or nurse to answer any questions you may have.**

**Tell your doctor or nurse if you notice any of the following and they worry you:**

- nausea and vomiting
- taste disturbances, metallic taste
- flushing.

These are the more common side effects of PENTAMIDINE-EMC. These side effects are usually mild.

**Tell your doctor or nurse immediately if you notice any of the following:**

- pain or redness at the injection site
- skin rash, redness, itching.

These may be serious side effects. You may need urgent medical attention.

**If any of the following happen, tell your doctor or nurse immediately or, if you are not in a hospital, go to the Accident and Emergency department at your nearest hospital:**

- signs of an infection such as sore throat or fever
- unusual bleeding or bruising
- signs of high blood sugar, which may include increased urination, unusual thirst, tiredness
- peeling of the skin
- signs of low blood sugar, which may include trembling or shaking, light-headedness, irritability
- dizziness or fainting, which may be signs of low blood pressure
- slow, fast or irregular heart rate
- pain in upper abdomen
- breathlessness, difficulty in breathing.
- Fever, chills, headache and muscle pain (signs of Herxheimer reaction)

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients.

**Tell your doctor or nurse if you notice anything that is making you feel unwell.**

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

## Storage

PENTAMIDINE-EMC will generally be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

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## Product description

### *What it looks like*

PENTAMIDINE-EMC is a white or almost white powder. It must be dissolved and further diluted before it is given.

### *Ingredients*

Active ingredient:

- Pentamidine Isetionate

There are no other ingredients.

PENTAMIDINE-EMC does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### *Sponsor*

**Emcure Pharmaceuticals Pty Ltd.**

### **Distributed by:**

**Luminarie Pty Ltd**

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PENTAMIDINE-EMC is available in the following strength:

- 300 mg /vial
- AUST R: 338274