

DBL™ Pentamidine Isethionate

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using DBL Pentamidine Isethionate?

DBL Pentamidine Isethionate contains the active ingredient pentamidine isetionate. DBL Pentamidine Isethionate is used to treat an infection called pneumocystis carinii pneumonia (PCP). DBL Pentamidine Isethionate can also be used to treat other types of protozoal infections, such as Leishmaniasis and Trypanosomiasis.

For more information, see Section [1. Why am I using DBL Pentamidine Isethionate?](#) in the full CMI.

2. What should I know before I use DBL Pentamidine Isethionate?

Do not use if you have ever had an allergic reaction to pentamidine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions or take any other medicines.

DBL Pentamidine Isethionate is Pentamidine is not recommended for use during pregnancy or breastfeeding. Speak to your doctor if you are pregnant, plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use DBL Pentamidine Isethionate?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Pentamidine Isethionate and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use DBL Pentamidine Isethionate?

- DBL Pentamidine Isethionate must only be given by a doctor or nurse. Your doctor will decide what dose of pentamidine you will receive.
- DBL Pentamidine Isethionate is given as a slow injection into a vein (intravenously) over a period of at least 60 minutes.

More instructions can be found in Section [4. How do I use DBL Pentamidine Isethionate?](#) in the full CMI.

5. What should I know while using DBL Pentamidine Isethionate?

Things you should do	<ul style="list-style-type: none">● If you become pregnant, or which to breastfeed, while being given pentamidine, tell your doctor immediately.● Remind any doctor or dentist you visit that you are using DBL Pentamidine Isethionate.● If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given pentamidine.
Driving or using machines	<ul style="list-style-type: none">● DBL Pentamidine Isethionate may cause dizziness and light-headedness in some people.
Drinking alcohol	<ul style="list-style-type: none">● Alcohol may worsen dizziness or light-headedness.
Looking after your medicine	<ul style="list-style-type: none">● DBL Pentamidine Isethionate will generally be stored in the

	pharmacy or on the ward.
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For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

Side effects may include nausea and vomiting, taste disturbance or metallic taste, pain or redness at the injection site, flushing of the skin or itching, hair loss, or hallucinations. More serious side effects may include signs of an infection such as sore throat, fever and muscle pain, unusual bleeding or bruising, dizziness or fainting, other changes to blood pressure or changes in urine.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DBL Pentamidine Isethionate

Isethionate

Active ingredient(s): *Pentamidine Isetionate* (pen-TAM-i-deen eye-se-THIO-nate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Pentamidine Isethionate. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DBL Pentamidine Isethionate.**

Where to find information in this leaflet:

- [1. Why am I using DBL Pentamidine Isethionate?](#)
- [2. What should I know before I use DBL Pentamidine Isethionate?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use DBL Pentamidine Isethionate?](#)
- [5. What should I know while using DBL Pentamidine Isethionate?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using DBL Pentamidine Isethionate?

DBL Pentamidine Isethionate contains the active ingredient pentamidine isetionate. DBL Pentamidine Isethionate 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).

DBL Pentamidine Isethionate can also be used to treat other types of protozoal infections, such as Leishmaniasis and Trypanosomiasis.

2. What should I know before I use DBL Pentamidine Isethionate?

Warnings

Do not use DBL Pentamidine Isethionate if:

1. you are allergic to pentamidine, or any of the ingredients listed at the end of this leaflet.

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.

Always check the ingredients to make sure you can use this medicine.

2. you are pregnant or intend to become pregnant. Please see 'pregnancy and breastfeeding' below.
3. you are breast-feeding or plan to breast-feed. Please see 'pregnancy and breastfeeding' below.

Check with your doctor if you:

- Have any other medical conditions, especially:

- 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.

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

- very low blood pressure, even after one dose
- very low blood sugar
- irregular heartbeat
- inflamed pancreas

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

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 breast-feeding, your doctor

will discuss with you the benefits and risks of being given it.

3. What if I am taking other medicines?

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

Some medicines may interfere with DBL Pentamidine Isethionate and affect how it works.

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

Medicines that are harmful to the liver, kidneys or blood cells may also interfere with pentamidine.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Pentamidine Isethionate.

4. How do I use DBL Pentamidine Isethionate?

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 DBL Pentamidine Isethionate is given and for how long

- DBL Pentamidine Isethionate is given as a slow injection into a vein (intravenously) over a period of at least 60 minutes. DBL Pentamidine Isethionate 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.
- To treat Pneumocystis carinii pneumonia (PCP), DBL Pentamidine Isethionate is usually given once daily for 14 days.
- To treat Leishmaniasis, DBL Pentamidine Isethionate may be given once, twice or three times a week.
- To treat Trypanosomiasis, DBL Pentamidine Isethionate may be given either daily or on alternate days for a total of 7 to 10 doses.

If you are given too much DBL Pentamidine Isethionate

As DBL Pentamidine Isethionate 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, or if you think that you have received too much DBL pentamidine isethionate, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using DBL Pentamidine Isethionate?

Things you should do

- If you become pregnant, or wish to breastfeed, while being given pentamidine, tell your doctor immediately.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given pentamidine.

- 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 sugar, heart rate, kidney and liver function tests) from time to time to make sure the medicine is working and to prevent unwanted side effects

Call your doctor straight away if you:

- Experience any unusual effects of this medicine, or any side effects listed under Section '6. Are there any side effects' below.

Remind any doctor or dentist you visit that you are using DBL Pentamidine Isethionate.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Pentamidine Isethionate affects you.

DBL Pentamidine Isethionate 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may worsen dizziness or light-headedness.

Looking after your medicine

DBL Pentamidine Isethionate will generally be stored in the pharmacy or on the ward

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal related symptoms:</p> <ul style="list-style-type: none">• nausea and vomiting• taste disturbances, metallic taste <p>Visible skin related changes:</p> <ul style="list-style-type: none">• pain or redness at the injection site	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • skin rash, redness, itching • flushing in face <p>Other</p> <ul style="list-style-type: none"> • hair loss • hallucinations 	

Serious side effects

Serious side effects	What to do
<p>Changes to the skin:</p> <ul style="list-style-type: none"> • unusual bleeding or bruising • peeling of the skin <p>Signs of an infection or reaction:</p> <ul style="list-style-type: none"> • sore throat or fever • fever, chills, headache and muscle pain (signs of Herxheimer reaction) <p>Changes to blood sugar:</p> <ul style="list-style-type: none"> • increased urination, unusual thirst, tiredness (signs of high blood sugar) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● trembling or shaking, light-headedness, irritability (signs of low blood sugar) <p>Blood pressure, heart rate or clothing:</p> <ul style="list-style-type: none"> ● dizziness or fainting (may be signs of low blood pressure) ● slow, fast or irregular heart rate ● pain, swelling, redness, skin tenderness, warmth, sudden shortness of breath, chest pain (signs of blood clot) <p>Breathing:</p> <ul style="list-style-type: none"> ● breathlessness, difficulty in breathing. <p>Urine changes and associated swelling:</p> <ul style="list-style-type: none"> ● less urine, change in the colour of your urine with swelling in your legs, ankles or feet <p>Other:</p>	

Serious side effects	What to do
<ul style="list-style-type: none"> • pain in upper abdomen 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What DBL Pentamidine Isethionate contains

Active ingredient (main ingredient)	Pentamidine isetionate
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Other ingredients (inactive ingredients)	There are no other ingredients.
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Do not take this medicine if you are allergic to any of these ingredients.

DBL Pentamidine Isethionate does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes

What DBL Pentamidine Isethionate looks like

DBL Pentamidine Isethionate is a white or almost white powder. It must be dissolved and further diluted before it is given.

300 mg per vial - AUST R 16260

Who distributes DBL Pentamidine Isethionate

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

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