D-PENAMINE®

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> 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 D-PENAMINE?

D-PENAMINE contains the active ingredient D-penicillamine. D-PENAMINE is used to treat severe, active rheumatoid arthritis, lead poisoning, Wilson's disease and cystinuria.

For more information, see Section <u>1. Why am I using D-PENAMINE?</u> in the full CMI.

2. What should I know before I use D-PENAMINE?

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

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use D-PENAMINE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with D-PENAMINE 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 D-PENAMINE?

- Your doctor will tell you how many tablets you need to take each day and when to take them.
- This depends on your condition and whether or not you are taking any other medicines.

More instructions can be found in Section <u>4. How do I</u> use D-PENAMINE? in the full CMI.

5. What should I know while using D-PENAMINE?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using D-PENAMINE.
- If you plan to undergo any surgical procedures, especially vascular surgery tell your doctor

	that you are taking D-PENAMINE. If you are about to have any blood tests, tell your doctor that you are taking this medicine.
Things you should not do	 Do not stop taking D-PENAMINE, or change the dose, even if you are feeling better without checking with your doctor. Do not use D-PENAMINE to treat any other conditions unless your doctor tells you to. Do not give D-PENAMINE to anyone else, even if they have the same condition as you.
Looking after your medicine	 Keep the tablets in a cool, dry place (below 25°C) in its original packaging. Keep the bottle tightly closed. Do not store D-PENAMINE in the bathroom, near a sink,

on a	window	sill	or	in	the
car.					

 Keep your tablets where children cannot reach it.

For more information, see Section <u>5. What should I know while using D-PENAMINE?</u> in the full CMI.

6. Are there any side effects?

Tell your doctor if you notice any of the following and they worry you: nausea, vomiting, diarrhoea, loss of appetite, impairment of taste, red or itchy rash accompanied by fever, joint pain, loss of hair, ringing in the ears, red, splitting lips, inflammation of the tongue, gums or mouth, swelling and redness along a vein which is extremely tender when touched, visual disturbances, muscle weakness, drooping eyelids, double vision, blisters on the skin, blisters containing dark blood, breast enlargement, inflammation of the blood vessels, symptoms of iron deficiency such as pale complexion and lowered vitality.

Tell your doctor immediately if you experience fever, sore throat, chills, bleeding or bruising more easily than normal.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

D-PENAMINE®

Active ingredient(s): D-penicillamine

Consumer Medicine Information (CMI)

This leaflet provides important information about using D-PENAMINE. 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 D-PENAMINE.

Where to find information in this leaflet:

- 1. Why am I using D-PENAMINE?
- 2. What should I know before I use D-PENAMINE?
- 3. What if I am taking other medicines?
- 4. How do I use D-PENAMINE?
- 5. What should I know while using D-PENAMINE?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using D-PENAMINE?

D-PENAMINE contains the active ingredient D- penicillamine. D-PENAMINE is a chelating agent.
This means that it binds to certain metals in the body including lead, copper, gold and mercury to help remove them from the body if necessary. D-PENAMINE is also

used to relieve the pain and stiffness of rheumatoid arthritis if other medicines and rest have not helped.

D-PENAMINE is used to treat the following conditions:

- severe, active rheumatoid arthritis (painful joint disease)
- lead poisoning
- Wilson's disease (a condition which results in too much copper in the body)
- cystinuria (a condition which can result in kidney stones).

Ask your doctor if you have any questions about why D-PENAMINE has been prescribed for you.

Your doctor may have prescribed D-PENAMINE for another reason.

D-PENAMINE is available only with a doctor's prescription.

2. What should I know before I use D-PENAMINE?

Warnings

Do not use D-PENAMINE if:

- you are allergic to D-PENAMINE or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - shortness of breath

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

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

- you are receiving gold therapy or taking anti-malarial medicines.
- the expiry date (EXP) printed on the pack has passed

If you take this medicine after the expiry date has passed, it may not work as well.

- the packaging shows signs of tampering
- the tablets do not look quite right

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- are allergic to any other medicines including penicillin, or any other substances such as foods, dyes or preservatives
- have, or have had, any medical conditions, especially the following:
 - kidney disease
 - liver disease

Your doctor may want to take special care if you have any of these conditions

If you have not told your doctor about any of the above, tell them before you start taking D-PENAMINE.

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 <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant, intend to become pregnant, are breast-feeding or intend to breast-feed.

D-PENAMINE is not recommended for use during pregnancy. If there is a need to consider D-PENAMINE during your pregnancy or breast-feeding, your doctor or pharmacist will discuss with you the benefits and risks of using 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 be affected by D-PENAMINE, or may affect how well it works. These include:

isoniazid, a medicine used to treat tuberculosis.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Take D-PENAMINE one hour apart from other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking D-PENAMINE.

4. How do I use D-PENAMINE?

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

- Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition and whether or not you are taking any other medicines.
- The usual starting dose for rheumatoid arthritis is no more than 250 mg daily for the first month. This dose is increased by the same amount at intervals of no

- less than one month until a daily dose of 1500 mg has been reached.
- For the treatment of Wilson's disease, the usual dose of D-PENAMINE is 1500 mg to 2000 mg a day.
- For the treatment of cystinuria, the usual dose of D-PENAMINE is 750 mg to 1000 mg a day in divided doses.
- For the treatment of lead poisoning, the usual dose of D-PENAMINE is 250 mg to 1000 mg a day in divided doses.

When to take D-PENAMINE

 Take D-PENAMINE on an empty stomach, for example, 1 hour before meals or 2 hours after meals, and at least one hour apart from any other medicine, food or milk.

How to take D-PENAMINE

Swallow the tablets whole with a glass of water.

How long to take D-PENAMINE for

 Keep taking D-PENAMINE for as long as your doctor recommends.

If you forget to use D-PENAMINE

 D-PENAMINE should be used regularly at the same time each day.

- If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.
- Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.
- Do not take a double dose to make up for the dose you missed.
- If you are not sure what to do or have any questions on this, ask your doctor or pharmacist.

If you use too much D-PENAMINE

If you think that you have used too much D-PENAMINE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 D-PENAMINE?

Things you should do

- Before starting any new medicine, tell your doctor or pharmacist that you are taking D-PENAMINE.
- Tell all the doctors, dentists and pharmacists who are treating you that you are taking D-PENAMINE.
- If you become pregnant while taking D-PENAMINE, tell your doctor.
- If you plan to undergo any surgical procedures, especially vascular surgery tell your doctor that you are taking D-PENAMINE.
 - Treatment with D-PENAMINE should, if possible, be discontinued for at least six weeks prior to surgery.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine.
 - D-PENAMINE may affect the results of some tests.
- Visit your doctor regularly so they can check on your progress.

Your doctor may do some tests to check your blood, liver and kidneys from time to time, to make sure the medicine is working and to prevent unwanted side effects.

Things you should not do

- Do not stop taking D-PENAMINE, or change the dose, even if you are feeling better without checking with your doctor.
- Do not use D-PENAMINE to treat any other conditions unless your doctor tells you to.
- Do not give D-PENAMINE to anyone else, even if they have the same condition as you.

Looking after your medicine

Keep D-PENAMINE where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they will not keep well.

Keep the bottle tightly closed.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store D-PENAMINE or any other medicine in the bathroom or near a sink.

Do not leave D-PENAMINE in the car or on window sills.

Heat and dampness can destroy this medicine.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking D-PENAMINE, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking D-PENAMINE.

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.

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

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
 nausea vomiting diarrhoea loss of appetite impairment of taste red or itchy rash accompanied by fever, joint pain loss of hair ringing in the ears The above list includes the more common side effects of D-PENAMINE. 	Speak to your doctor if you have any of these less serious side effects and they worry you.
 red, splitting lips inflammation of the tongue, gums or mouth swelling and redness along a vein which is extremely tender when touched visual disturbances muscle weakness, drooping eyelids, double vision blisters on the skin 	

Less serious side effects	What to do
 blisters containing dark blood 	
breast enlargement	
inflammation of the blood vessels	
 Goodpasture's syndrome, a syndrome characterised by coughing with production of mucous containing frothy, bright red blood; nausea; constipation; itching; less frequent urination symptoms of iron deficiency such as pale complexion and lowered vitality. All of the above side effects are very rare 	
effects are very rare.	

Serious side effects

Serious side effects	What to do
 Fever sore throat chills bleeding bruising more easily than normal These are serious side effects which require medical attention. 	Call your doctor straight away if you notice any of these serious side effects.

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 D-PENAMINE contains

Active ingredient (main ingredient)	D-PENAMINE contains either 125 mg or 250 mg of D-penicillamine
Other ingredients	The tablets also contain:
(inactive ingredients)	• povidone
	microcrystalline cellulose
	• stearic acid
	 sodium starch glycollate.
	The tablet coating contains:
	 hydroxypropyl methylcellulose glycerol titanium dioxide (E171)
Potential allergens	D-PENAMINE tablets contain sulfites.

Do not take this medicine if you are allergic to any of these ingredients.

What D-PENAMINE looks like

D-PENAMINE tablets are available in 2 strengths:

- D-PENAMINE 125 mg tablets are round, white to offwhite regular biconvex coated tablets, upper surface embossed 'DS' lower surface embossed '125'. (AUST R 14625)
- D-PENAMINE 250 mg tablets are round, white to offwhite regular biconvex coated tablets, upper surface embossed 'DM' lower surface embossed '250'. (AUST R 14626)

Each bottle contains 100 tablets.

Who distributes D-PENAMINE

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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D-PENAMINE® is a Viatris company trade mark

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