### **Consumer Medicine Information**

### What is in this leaflet

This leaflet answers some common questions about D-PENAMINE.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking D-PENAMINE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

#### Keep this leaflet with your medicine.

You may need to read it again.

#### What D-PENAMINE is used for

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.

### Before you take D-PENAMINE

Tell your doctor if you have any of the following conditions or if you have ever experienced any of these conditions.

When you must not take it

Do not take D-PENAMINE if you have had an allergic reaction to D-PENAMINE or to any of the ingredients listed at the end of this leaflet (see 'Product Description').

Signs of an allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue.

Do not take D-PENAMINE if you are receiving gold therapy or taking anti-malarial medicines.

Do not take D-PENAMINE if the expiry date printed on the pack has passed.

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

Do not take D-PENAMINE if the packaging shows signs of tampering.

Do not take D-PENAMINE if the tablets do not look quite right.

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

Before you start to take it

### Tell your doctor if you have allergies to:

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

Tell your doctor if you 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.

## 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.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a 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.

### How to take 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.

How to take D-PENAMINE

Swallow the tablets whole with a glass of water.

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 long to take D-PENAMINE for

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

If you forget to take D-PENAMINE

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 take too much D-PENAMINE (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much D-PENAMINE. Do this even if there are no signs of discomfort or poisoning.

### While you are taking D-PENAMINE

Things you must 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 must 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.

### Side effects

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

Like all other medicines, D-PENAMINE may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

You may not experience any of them.

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

### 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.

The above list includes the more common side effects of D-PENAMINE.

## Tell your doctor if you notice any of the following 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
- blisters containing dark blood
- breast enlargement
- 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.

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

These are serious side effects which require medical attention.

### Tell your doctor if you notice anything that is making you feel unwell.

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

### After taking D-PENAMINE

### Storage

### 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  $25^{\circ}\mathrm{C}$ .

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.

### Disposal

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.

### Product description

#### What it looks like

D-PENAMINE tablets are available in 2 strengths:

- 125 mg tablets are white, round marked "DS" on one side and "125" on the reverse
- 250 mg tablets are white, round marked "DM" on one side and "250" on the reverse.

Each bottle contains 100 tablets.

### Ingredients

The active ingredient in D-PENAMINE is D-penicillamine. Each D-PENAMINE tablet contains either 125 mg or 250 mg of D-penicillamine.

The tablets also contain:

- povidone
- cellulose-microcrystalline
- stearic acid
- sodium starch glycollate.

The tablet coating contains:

- hydroxypropyl methylcellulose
- glycerol
- titanium dioxide (E171).

The tablets are gluten free.

### Manufacturer

D-PENAMINE is made in Australia by:

Alphapharm Pty Limited (ABN 93 002 359 739) Chase Building 2 Wentworth Park Road Glebe NSW 2037

Phone: (02) 9298 3999 Medical Information Phone: 1800 028 365 www.alphapharm.com.au

Australian registration numbers:

D-PENAMINE 125 mg - AUST R 14625 D-PENAMINE 250 mg - AUST R 14626 D-PENAMINE® is a registered trade mark.

This leaflet was prepared on

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