

PACKAGE LEAFLET

Package leaflet: Information for the patient

Penicillamine 125 mg film-coated tablets

Penicillamine 250 mg film-coated tablets

(penicillamine)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Penicillamine is and what it is used for.
2. What you need to know before you take Penicillamine.
3. How to take Penicillamine.
4. Possible side effects.
5. How to store Penicillamine.
6. Contents of the pack and other information.

1. What Penicillamine is and what it is used for

Penicillamine belongs to a group of medicines called disease modifying antirheumatic drugs (DMARDs). DMARDs work by reducing the body's immune response and the symptoms of rheumatoid arthritis.

Penicillamine helps to relieve the pain and stiffness caused by rheumatoid arthritis. It is used when other medicines for rheumatoid arthritis have not worked.

Penicillamine is also a chelating agent. This means that it can bind to certain metals in your body, including lead and copper, to help remove them from your body.

Penicillamine is used in adults and children to treat:

- serious, active rheumatoid arthritis, including Still's disease in children
- Wilson's disease, a condition where the body cannot get rid of copper properly
- a kidney problem called cystinuria
- lead poisoning.

Penicillamine is used in adults only to treat:

- chronic active hepatitis – a type of liver disease.

Penicillamine is not a painkiller so you should not expect to feel better straight away. It will be a few weeks before your joints feel less stiff and painful.

2. What you need to know before you take Penicillamine

Your doctor will ask you to have blood tests to check your blood count and kidney function before you start taking Penicillamine. He or she will test your blood and urine regularly while you are taking Penicillamine. This is so that your doctor can check for any side effects and adjust your dose if necessary.

Do not take Penicillamine:

- if you are allergic to penicillamine or any of the other ingredients of this medicine (listed in section 6)
- if you have ever had agranulocytosis (reduction in the number of white blood cells) after taking penicillamine
- if you have ever had aplastic anaemia (a severe reduction in blood cells which can cause weakness, bruising or make infections more likely) after taking penicillamine
- if you have ever had lupus erythematosus (LE), an allergic condition which causes skin rashes
- if you suffer from kidney problems
- if you have thrombocytopenia (a blood disorder which causes bleeding into your skin, bruising and more bleeding than usual after an injury) after taking penicillamine.

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before you take Penicillamine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Penicillamine, particularly if any of the following applies to you:

- if you have ever had side effects with gold or you are currently taking medicines that contain gold
- if you have protein in your urine
- if you are pregnant, trying to become pregnant or breast-feeding
- if you have blood in your urine
- if you have leucopenia (a blood disorder which causes susceptibility to infection)
- if you are elderly.

Your doctor should carry out full blood and urine tests:

- weekly or fortnightly for the first 8 weeks of treatment, and then monthly
- whenever your dose of penicillamine is increased.

If you are taking Penicillamine for Wilson's disease or for cystinuria, your doctor may carry out these tests at less regular intervals.

Your doctor may tell you to stop taking Penicillamine if:

- your thrombocyte count or your white blood cell count fall below certain levels, or
- either count falls for three tests in a row.

If, after stopping your tablets your blood cell counts return to normal, you may be able to restart treatment at a lower dose. If, after restarting your tablets at a lower dose you develop low blood counts again, you should permanently stop taking this medicine.

Other medicines and Penicillamine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Penicillamine may increase the risk of side effects if you also take the following medicines:

- gold (used to treat rheumatoid arthritis)
- NSAIDs (non-steroidal anti-inflammatory drugs) e.g. ibuprofen or naproxen (used to treat arthritis and for pain relief) as there is an increased risk of damaging your kidneys
- clozapine (used to treat schizophrenia) as taking Penicillamine with clozapine may increase the potential side effects on the bone marrow.

The effectiveness of Penicillamine may be altered if you also take the following medicines:

- iron therapy (used to treat low iron levels or anaemia). Take the iron at least two hours before or after taking Penicillamine
- antacids (used to neutralise acid in your stomach). Take the antacids at least two hours before or after taking Penicillamine

- zinc (used to treat low zinc levels), concomitant use may reduce the effect of both medicine.

Penicillamine may affect how well the following medicines work:

- digoxin (used for an irregular heartbeat).

Your doctor may give you pyridoxine (vitamin B6) if you are taking Penicillamine long term, especially if you are on restricted diet.

Penicillamine with food and drink

Penicillamine should be taken on an empty stomach, and at least half an hour (one hour for children with Wilson's disease or cystinuria) before a meal, with a drink of water.

Pregnancy and breast-feeding

You **should not** take Penicillamine if you are pregnant.

Penicillamine may reach your baby through the breast milk. Therefore, you **should not** take Penicillamine if you are breast-feeding.

If your doctor considers that treatment is absolutely essential, he may tell you to take Penicillamine even when you are pregnant or breast-feeding. This will depend on your condition and the disease you have.

If you are pregnant or breast feeding, think you may be pregnant or are planning to have baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Penicillamine is not known to affect your ability to drive or use machines.

Penicillamine contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take penicillamine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You will have regular blood and urine tests, especially when you start taking the tablets and when you increase the dose. These are to check for changes in your blood cell counts and to look for protein or blood in your urine.

The recommended dose for each condition is given below.

Use in adults

Rheumatoid Arthritis:

Take 125 mg to 250 mg per day for the first month. Your doctor will then tell you how to increase the dose gradually over several months until your symptoms get better. Your doctor will monitor you closely until a minimum daily dose is found that controls your symptoms (your maintenance dose).

This may take some months. The usual maintenance dose is 500 mg to 750 mg per day but may be as high as 1500 mg per day.

It may be several months before you feel better. If there is no improvement after taking the tablets for 1 year, your doctor will tell you to stop taking the tablets. If your symptoms are controlled continuously for 6 months, your doctor may reduce your daily dose.

Wilson's disease:

The recommended dose is between 1500 mg to 2000 mg per day in divided doses. If your symptoms are controlled, your doctor may reduce your dose. You should not take a dose of 2000 mg or more per day for more than 12 months.

Cystinuria:

Your doctor will take a sample to measure the amount of cystine (an amino acid) in your urine. From this he will be able to work out the lowest dose that will still be effective for you.

Prevention of cystine stones: 500 mg to 1000 mg at bedtime. It is important that you drink enough fluids (not less than 3 litres per day).

Dissolving cystine stones: 1000 mg to 3000 mg per day, in divided doses.

Lead Poisoning:

1000 mg to 1500 mg per day, in divided doses until your doctor tells you that the amount of lead in your urine is normal.

Active chronic hepatitis:

Your doctor should take a blood sample regularly to check that your liver is working well.

For maintenance, initially 500 mg per day in divided doses, increasing over 3 months to a maintenance dose of 1250 mg per day.

Use in elderly

Rheumatoid Arthritis:

The recommended dose is 125 mg daily for the first month. Your doctor will then tell you how to increase the dose gradually over several months until you are feeling better. You should not take more than 1000 mg daily.

It may be several months before you feel better. If there is no improvement after taking the tablets for 1 year, your doctor will tell you to stop taking the tablets. If you stay well for six months your doctor may reduce your dose.

Wilson's disease:

Your dose will depend on your weight. The recommended dose is 20 mg a day for each kilogram of body weight in divided doses. Your doctor will reduce the dose over time to find the minimum necessary to control your disease.

Cystinuria:

Your doctor will determine your dose.

Lead poisoning:

Your dose will depend on your weight. The recommended dose is 20 mg a day for each kilogram of body weight in divided doses, until your doctor tells you the amount of lead in your blood is normal.

Active Chronic Hepatitis:

Penicillamine is not recommended for the treatment of active chronic hepatitis in the elderly.

Use in children

The dose may depend on the weight of the child. As the smallest available tablet is 125 mg, it might be too large for very small children.

Rheumatoid arthritis:

The recommended dose is 15 mg to 20 mg a day for each kilogram of body weight. You will start with a low dose for the first month and increase gradually.

Wilson's disease:

For children under 12 years, 20 mg a day for each kilogram of body weight in two or three separate doses given 1 hour before meals. For older children the usual dose is 750 mg to 1000 mg daily.

Cystinuria:

The recommended starting dose is 20 mg to 30 mg for each kilogram of body weight, in two or three separate doses given 1 hour before meals. Your doctor may change your dose depending on the results of the tests on your urine.

Lead poisoning:

The recommended dose is 15 mg to 20 mg a day for each kilogram of body weight, in two or three separate doses.

Active chronic hepatitis:

Penicillamine is not recommended for the treatment of active chronic hepatitis in the paediatric population.

If you have kidney problems your doctor will start you on a lower dose.

Method of administration

When taking Penicillamine:

- swallow the tablets with water
- always take your tablets at least half an hour (or 1 hour for children) before a meal, or at bedtime
- if you are taking iron tablets, antacids or digoxin take them at least two hours before or after you have taken penicillamine
- take your tablets as long as your doctor tells you to
- do not take more tablets than your doctor tells you to.

If you take more Penicillamine than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice.

If you forget to take Penicillamine

Unless it is almost time for the next dose, take it as soon as you remember, then just carry on as before. **Do not** take a double dose to make up for a forgotten tablet.

If you stop taking Penicillamine

Do not stop or change your treatment before talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor or go to your nearest hospital emergency department immediately if you think you may have any of the following serious side effects:

Common: may affect up to 1 in 10 people

- bruising more easily, nose bleeds and/or bleeding gums more often. These may be signs of a blood disorder called thrombocytopenia.

Rare: may affect up to 1 in 1,000 people

- allergic reactions which includes sudden wheeziness, chest pain, difficulty in breathing, sudden swelling, fever, skin rash or itching
- blood in your urine.

Not known: frequency cannot be estimated from the available data

- blood reactions that may cause unusual bleeding or bruising of the skin, may reduction of the number of white cells in your blood, causing more infections than usual
- fever, severe chills, sore throat or mouth ulcer, feeling of extreme tiredness or weakness, paleness of the skin and more susceptible to infections. These may be signs of anaemia
- breakdown of the tissues of your kidney (nephrotic syndrome)
- blistering skin rash or severe skin reactions, blistering of the skin, mouth, throat, nose, eyes and genitals (Stevens-Johnson syndrome or pemphigus)
- damage to your kidneys and bleeding in your lungs caused by your body's immune system (Goodpasture's syndrome)
- coughing up blood (pulmonary haemorrhage)
- inflammation of the pancreas with severe upper stomach pain, feeling and being sick (pancreatitis).

Other side effects that can occur:

Very common: may affect more than 1 in 10 people

- protein in your urine (this is detected by a urine test).

Rare: may affect up to 1 in 1,000 people

- sore mouth, mouth ulcer
- swollen breast tissue
- hair loss
- wrinkly skin
- abnormalities of the elastic fibres in the skin which cause clusters of the small reddish bumps usually on the neck or arms.

Not known: frequency cannot be estimated from the available data

- loss of taste
- feeling sick (especially at the start of treatment) or being sick
- loss of appetite (especially at the start of treatment)
- jaundice (yellowing of the skin or eyes) as a result of liver or blood problems (this may include changes in blood test which show how your liver is working)
- lung problems (e.g. wheezing, coughing or difficulty in breathing)
- a condition that causes nails to become thicker and yellow or greenish-yellow in colour, chronic swelling in the limbs (hand and feet) and chronic breathing problem
- redness, a rash or itching (especially at the start of treatment)
- fever (especially at the start of treatment) or frequent infections
- muscle weakness and tiredness (sometimes with skin rashes)
- worsening of the pain and swelling in your joints
- lupus erythmatosus (an allergic condition which causes joint pain, skin rashes and fever)
- newly diagnosed rheumatoid arthritis.

After several months or years of therapy you may develop a particular rash that makes your skin fragile called acquired epidermolysis bullosa or penicillamine dermatopathy. If you get this your doctor may tell you to take a lower dose.

If you suffer from rheumatoid arthritis you should tell your doctor if your joints become more painful, swollen, red or hot because medicines like Penicillamine sometimes cause joint infections.

If you suffer from Wilson's disease you should tell your doctor if you experience:

- a worsening of muscle spasms
- muscle stiffness
- tremor or slurred speech.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Penicillamine

Keep this medicine out of the sight and reach of children.

Store your tablets in a cool, dry place below 25°C.

Do not use this medicine after the expiry date which is stated on the bottle after 'EXP'. The expiry date refers to the last day of that month.

Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Penicillamine film-coated tablets contain

The active substance is penicillamine. Each 125 mg tablet contains 125 mg penicillamine. Each 250 mg tablet contains 250 mg penicillamine.

The other ingredients are:

povidone, lactose, sodium starch glycolate, magnesium stearate. The film-coat contains: hydroxypropyl, methylcellulose (E464), titanium dioxide (E171), polyethylene glycol, carnauba wax.

What Penicillamine looks like and contents of the pack

Your medicine comes as a round, white film coated tablet. On one side, the 125 mg tablet is embossed with 'PC 125' and marked 'G' on the reverse, the 250 mg is embossed with 'PC 250' on one side and marked 'G' on the reverse.

Penicillamine film-coated tablets are available in polypropylene containers with polyethylene caps in packs of 5, 7, 10, 14, 15, 20, 21, 25, 28, 30, 56, 60, 84, 90, 100, 112, 120, 168, 180, 250 and 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Herts, EN6 1TL, United Kingdom.

Manufacturer

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

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