

PATIENT INFORMATION LEAFLET

PENICILLAMINE 125MG AND 250MG TABLETS

(penicillamine)

Read all of this leaflet carefully before you start taking this medicine.

- **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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.**
- **If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

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1. WHAT PENICILLAMINE TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Penicillamine 125mg Tablets or Penicillamine 250mg Tablets. Penicillamine belongs to a group of medicines called disease modifying anti-rheumatic drugs (DMARDs).

Penicillamine works by reducing the body's immune response and relieving pain, swelling and stiffness caused by rheumatoid arthritis. Penicillamine is also a chelating agent. This means that it binds to certain metals in your body, including lead and copper, to help to 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 TABLETS

Your doctor will ask you to have a blood test and urine test before you start taking Penicillamine Tablets to check your blood count and kidney function. Your doctor will continue to test your blood and urine regularly while you are taking Penicillamine Tablets. If the tests show a low blood count or evidence of kidney damage, your doctor may decide to decrease your dose for a short time or stop your treatment completely.

Do not take Penicillamine Tablets if you:

- are allergic (hypersensitive) to penicillamine or any of the other ingredients in these tablets (See section 6, Contents of the pack and other information). Signs of an allergic reaction include rash, itching, swelling of the face, fainting and breathing problems.
- have severe kidney problems
- have lupus erythematosus (an auto-immune disorder)
- have a history of suffering from blood disorders after taking penicillamine e.g. agranulocytosis (a low white cell blood count), aplastic anaemia (symptoms include feeling tired, breathless, having pale skin and more susceptible to infection) or thrombocytopenia (a blood disorder which causes bleeding into your skin, bruising and bleeding more than normal)

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

Take special care with Penicillamine if you:

- are allergic (hypersensitive) to penicillin as you may have a similar reaction to penicillamine
- have ever had side effects with gold treatment
- are also taking NSAIDs (non-steroidal anti-inflammatory drugs)
- are elderly - as you may be at greater risk of suffering side effects
- have kidney problems
- are due to have surgery, as your doctor may need to reduce the amount of penicillamine you are taking
- have protein or blood in your urine
- are pregnant, trying to become pregnant or breast-feeding
- notice increased susceptibility to infection (for example, sore throats or mouth ulcers) or unexplained bleeding and bruising. These may be a sign of a decrease in blood cells and further laboratory tests should be carried out.
- are taking iron tablets, antacids or digoxin (used to treat heart failure). Take them at least two hours before or after you have taken penicillamine.

are taking penicillamine over a long time, especially if you are on a restricted diet, as it increases the requirement for pyridoxine (Vitamin B₆) so your doctor may also prescribe this vitamin for you are receiving treatment for rheumatoid arthritis as the response to penicillamine is often slow and the use of existing analgesics, anti-inflammatories or steroids should be continued and later gradually withdrawn, subject to improvement

- have a blood disorder or kidney problems as a full blood count and urinalysis (a test used to detect and assess a wide range of disorders) should be performed weekly for at least the first 2 months of therapy, (or after any change in dose) and should be repeated monthly thereafter.

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines as they may interfere with Penicillamine:

- iron therapy (used to treat low iron levels or anaemia) – if you are taking iron, it should be taken at least 2 hours before or after taking Penicillamine
- gold treatment (used to treat rheumatoid arthritis)
- digoxin (used to treat heart conditions) - if you are taking digoxin, it should be taken at least 2 hours before or after taking Penicillamine

- antacids (used to treat indigestion) - if you are taking antacids, they should be taken at least 2 hours before or after taking Penicillamine
- non-steroidal anti-inflammatory drugs (NSAIDs) (e.g. ibuprofen, indometacin, naproxen, oxyphenbutazone, phenylbutazone - used to relieve pain, inflammation and stiffness in joints and muscles)
- chloroquine or hydroxychloroquine (used to treat malaria)
- clozapine (used to treat the mental illness schizophrenia)
- levodopa (used in the treatment of Parkinson's disease)
- cytotoxic drugs (medicines to treat cancers)
- immunosuppressive drugs (medicines given following an organ transplant)
- zinc

Please tell your doctor or pharmacist if you are taking or have recently taken/used any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility

Tell your doctor if you are pregnant, planning to become pregnant or if you are breast-feeding, as small amounts of Penicillamine can pass into breast milk. Always ask your doctor or pharmacist for advice before taking any medicine.

Taking 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.

Driving and using machines

Penicillamine may cause dizziness, confusion and problems with your vision. If you are affected by any of these side effects do not drive or use machines.

3. HOW TO TAKE PENICILLAMINE TABLETS

Always take Penicillamine Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You should swallow Penicillamine Tablets with a glass of water. Penicillamine Tablets should be taken on an empty stomach at least half an hour before meals or before you go to bed. The dose you take will depend on what you are taking Penicillamine for.

Adults

Rheumatoid arthritis Take 125mg - 250mg a day for the first month. Your doctor will increase the dose slowly up to 500mg - 750mg daily (in divided doses). Your doctor may prescribe a dose as high as 1500mg. If there is no improvement in your condition after 12 months, your doctor might stop your Penicillamine treatment. If you stay well for six months your doctor may reduce your dose.

Wilson's Disease Take 1500mg - 2000mg daily in divided doses. Do not take more than 2000mg in one day. Your doctor may reduce your dose to 750mg - 1000mg daily once your condition is controlled. A dose of 2000mg daily should not be continued for more than 12 months.

Cystinuria To treat cystinuria take 1000mg - 3000mg daily in divided doses.

	To prevent cystinuria take 500mg - 1000mg before going to bed.
Lead poisoning	Take 1000mg - 1500mg daily in divided doses until your doctor tells you that the amount of lead in your urine is normal.
Chronic active hepatitis	Start by taking 500mg daily in divided doses. Your doctor will increase the amount of tablets you take over 3 months to 1250mg daily.
Elderly	
Rheumatoid arthritis	Take 125mg daily, in divided doses for the first month of treatment. Your doctor may increase the number of tablets you take over the next 3 months until you begin to feel better. Do not take more than 1000mg in one day. It may take several months before you feel better. If there is no improvement after taking tablets for 12 months, 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	The number of tablets you take will depend on your body weight. The usual dose is 20mg per kg body weight daily in divided doses. Your doctor will reduce your dose over time to find the minimum dosage required to control your disease.
Cystinuria	Your doctor will decide the number of tablets you should take.
Lead poisoning	The number of tablets you take will depend on your body weight. The usual dose is 20mg per kg body weight daily in divided doses until your doctor tells you that the amount of lead in your urine is normal.
Chronic active hepatitis	Penicillamine is not recommended for the treatment of chronic active hepatitis in the elderly.
Children	
	The dose may depend on the weight of the child. As the smallest available tablet is 125mg, it might be too large for very small children.
Rheumatoid arthritis	15mg to 20mg 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 20mg 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 0.75g to 1g daily.
Cystinuria	Start with 20 - 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 tests on your urine.
Lead poisoning	15mg - 20mg a day for each kilogram of body weight, in 2 to 3 separate doses.

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

If you are not sure how many tablets to take, ask your doctor or pharmacist.

If you take more of your medicine than you should

If you take more of your medicine than you should, contact your doctor or nearest hospital emergency department immediately. Take this leaflet and any remaining tablets with you to show the doctor.

If you forget to take your medicine

If you forget to take your medicine take it as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for the forgotten dose.

If you stop taking your medicine

Do not stop taking your medicine without talking to your doctor, even if you feel better. It is important that you take the full course of Penicillamine prescribed by 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 Penicillamine Tablets can cause side effects, although not everybody gets them.

STOP TAKING Penicillamine Tablets and contact your doctor immediately if you:

- have an allergic reaction causing difficulty breathing, wheezing, tightness of the chest, fever, swelling of the face, throat or tongue, sore, dry, itchy skin or severe skin rashes
- pass blood in your urine
- bruise more easily, get nose bleeds and/or bleeding gums more often. These may be signs of a blood disorder called thrombocytopenia.
- have a feeling of extreme tiredness or weakness, paleness of skin and are more susceptible to infections. These may be signs of anaemia.
- have a high temperature and ulcers or swelling of the mouth and throat
- have blistering of the skin, mouth, eyes and genitals

Please tell your doctor or pharmacist if you notice any of the following side effects

Very common side effects (more than 1 in 10 patients)

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

Rare side effects (more than 1 in 10,000 patients)

- soreness or swelling of the mouth or tongue
- clusters of small lumps usually on the neck or arms
- loss of hearing
- wrinkly or loose skin
- hair loss
- swelling of the breast tissue in men and women

Other possible side effects include

- diarrhoea
- muscle weakness
- loss of taste (reversible)
- feeling or being sick (especially at the start of treatment)
- fever or frequent infections
- lupus erythematosus (allergic condition, causes joint pain, skin rashes and fever)
- lung problems (e.g. wheezing, coughing, difficulty breathing, or bleeding)
- abnormal liver function, jaundice (skin or the whites of your eyes become yellow)

- inflammation of the pancreas - symptoms may include severe stomach and back pain
- developing rheumatoid arthritis (pain and inflammation of the joints) since starting your penicillamine treatment
- worsening of pain and swelling in your joints
- headache
- confusion
- changes in eyesight
- feeling dizzy or confused
- loss of appetite (especially at the start of treatment)
- blistering, swollen skin
- skin rash, redness or itching of skin – a rash may appear after several months or years of treatment, which may necessitate a reduction in dosage
- yellow nail syndrome (a condition causing thickening and yellow discolouration of nails, chronic swelling in the limbs and chronic respiratory problems)
- Iron deficiency may occur in menstruating women

Antihistamines, corticosteroids, or temporary reduction of dose will control allergic phenomena occurring early, unless severe.

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

If you suffer from Wilson’s disease tell your doctor if you experience

- worsening of muscle spasms
- muscle stiffness
- tremors (involuntary movements)
- slurred speech

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the internet 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 TABLETS

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use Penicillamine Tablets after the expiry date, which is shown on the pack. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the container tightly closed.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Penicillamine Tablets contain

The active substance is penicillamine. The other ingredients are maize starch, silicon dioxide, disodium edetate, poly (1-vinyl-2-pyrrolidone), microcrystalline cellulose, talc, magnesium stearate, mannitol, gelatin, polyethylene glycol, titanium dioxide, copolymerisate of ethyl acrylate-methyl acrylate (2 + 1), polysorbate, sodium carboxymethylcellulose and simethicone.

What Penicillamine Tablets look like and contents of the pack

Your medicine comes as white tablets containing either 125mg or 250mg of penicillamine.

Penicillamine 125mg tablets are white, biconvex, oblong film-coated tablets, plain on both sides.

Penicillamine 250mg tablets are white, biconvex, oblong film-coated tablets, plain on one side and scored on the other.

Penicillamine Tablets are available in packs of 4, 56 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

Company responsible for release of this medicine

Kent Pharmaceuticals Limited, Crowbridge Road, Ashford, Kent TN24 0GR, U.K.

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

Distributor

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