PATIENT INFORMATION LEAFLET

Distamine® 125/250mg Film-coated 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.

The information in this leaflet has been divided into the following sections:
1. What Distamine is and what it is taken for
2. Check before you take Distamine
3. How to take Distamine
4. Possible side effects
5. How to store Distamine
6. Further information

1. What Distamine is and what it is taken for

Distamine 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.

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

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

Distamine 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

Distamine is used in adults only to treat:
chronic active hepatitis - a type of liver disease.

Distamine 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. Check before you take Distamine

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

**Do not take Distamine:**
- if you are allergic (hypersensitive) to penicillamine or any of the ingredients of Distamine (see Section 6 Further information)
- if you have ever had agranulocytosis (a low white blood cell count) 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, speak to your doctor or pharmacist before you take Distamine.

**Take special care with Distamine**
Before you take Distamine tell your doctor:
- 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.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Distamine.
Taking other medicines
Tell your doctor or pharmacist if you are taking or have recently taken/used any of the following medicines as they may interfere with Distamine:

- **gold** - (used to treat rheumatoid arthritis) as there is an increased risk of getting side effects.

- **iron therapy** - (used to treat low iron levels or anaemia) as the effect of Distamine will be reduced if taken with iron. Therefore take the iron at least two hours before or after taking Distamine.

- **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.

- **antacids** - (used to neutralise acid in your stomach) as the effect of Distamine will be reduced if taken with antacids. Therefore take the antacids at least two hours before or after taking Distamine.

- **digoxin** - (used for an irregular heartbeat) as the effect of digoxin will be reduced if taken with Distamine.

- **clozapine** - (used to treat schizophrenia) as taking Distamine with clozapine may increase the potential side effects on the bone marrow.

- **zinc** - (used to treat low zinc levels) the effect of Distamine and/or zinc will be reduced if taken together.

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

Your doctor may give you pyridoxine (Vitamin B6) if you are taking Distamine long term, especially if you are on a restricted diet.
Taking with food and drink
Distamine 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
Tell your doctor if you are pregnant, trying to become pregnant or are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

3. How to take Distamine

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

When taking Distamine:
• swallow the tablets with water
• always take your tablets at least half an hour 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 Distamine
• take your tablets for as long as your doctor tells you to
• do not take more tablets than your doctor tells you to.

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

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 usual dose for each condition is given below.

Adults
Rheumatoid arthritis:
Take 125mg to 250mg a day for the first month. Your doctor will then tell you how to increase the dose gradually over several months until you are feeling better. Your doctor may then change your dose to keep you well. This new dose is usually 500mg to 750mg a day, but it can be as high as 1500mg.

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:
Take 1500mg to 2000mg a day spread over three or four doses. Once you are better, your doctor may reduce your dose. It is best not to take 2000mg a day for more than a year.

Cystinuria:
If you have cystine stones your dose will be 1000mg to 3000mg a day. If you are taking the tablets to prevent stones you will take 500mg to 1000mg at bedtime.

Lead poisoning:
Take 1000mg to 1500mg a day in three or four doses until your doctor tells you that the amount of lead in your urine is normal.

Chronic active hepatitis:
Start with 500mg a day. Your doctor will gradually increase the dose over three months, to 1250mg a day.

The elderly
Rheumatoid arthritis:
Take 125mg a day 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 1000mg in a single dose.

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 usual dose is 20mg a day for each kilogram of body weight. 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 usual dose is 20mg a day for each kilogram of body weight until your doctor tells you the amount of lead in your blood is normal.

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 are not sure how many tablets to take, ask your doctor or pharmacist or the staff at the hospital you visit for tests and treatment.

**What to do if you take more Distamine than you should**
If you take too many tablets by mistake, or someone else takes any of your medicine by accident, you should tell your doctor at once or contact your nearest accident and emergency department. Show any left-over medicines or the empty packet to the doctor.

**If you forget to take Distamine**
If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose.

Do not take a double dose. Then go on as before. If you miss several doses, tell your doctor.

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

### 4. Possible side effects

Do not worry. Like all medicines, Distamine can cause side effects, although not everyone gets them.

Contact your doctor immediately if:
• you have an allergic reaction which includes sudden wheeziness, chest pain, difficulty in breathing, sudden swelling, fever, skin rash or itching
• you feel weak and are more susceptible to infection
• you have fever and ulcers in the mouth or throat
• you notice blood in your urine
• you have blistering of the skin, mouth, eyes and genitals
• you notice bleeding into your skin, bruising and more bleeding than usual after an injury.

Very common side effects (more than 1 in 10 patients) of Distamine include:
• protein in your urine (this is detected by a urine test).

Rare side effects (more than 1 in 10,000 patients) of Distamine include:
• sore mouth
• swollen breast tissue
• hair loss
• wrinkly skin
• abnormalities of the elastic fibres in the skin which cause clusters of small reddish bumps usually on the neck or arms

Other side effects of Distamine include:
• loss of taste
• feeling or being sick (especially at the start of treatment)
• loss of appetite (especially at the start of treatment)
• severe stomach and back pain
• jaundice which is the yellowing of the skin or eyes as a result of liver or blood problems (this may include changes in blood tests which show how your liver is working)
• yellow nail syndrome (a condition causing thickening and yellow discolouration of nails, chronic swelling in the limbs and chronic respiratory problem)
• lung problems (e.g. wheezing, coughing or difficulty breathing)
• redness, a rash or itching
• fever or frequent infections
• blistering, swollen skin
• muscle weakness
• worsening of the pain and swelling in your joints
• lupus erythematosus (an allergic condition which causes joint pain, skin rashes and fever)
• newly diagnosed with rheumatoid arthritis

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

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 or call Freephone 0808 100 3352. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Distamine

Keep out of the reach and sight of children.

Do not take Distamine after the expiry date {EXP: mm yyyy} which is stated on the carton and tablet container. The expiry date refers to the last day of that month.

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

Do not take Distamine if you notice the appearance of the tablets has changed in any way.

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

6. Further information

What is in Distamine?
The active ingredient in this medicine is penicillamine.

The other ingredients are:
- tablet core: microcrystalline cellulose, sodium starch glycolate (Type A), povidone and magnesium stearate
- film-coating: glycerol, titanium dioxide (E171) and hypromellose.

What Distamine looks like and contents of the pack
The tablets come in two strengths (different sized tablets).

Each Distamine tablet contains either 125mg (milligrams) or 250mg D-penicillamine base (active ingredient) in bottles of 100 tablets.
They all have a white coating. The 125mg tablets are 8mm (millimetres) across and are marked DS on one side and 125 on the other. The 250mg tablets are 10mm across and are marked DM on one side and 250 on the other.

**Marketing Authorisation Holder and Manufacturer**
The marketing authorisation holder is: Alliance Pharmaceuticals Limited, Avonbridge House, Chippenham, Wiltshire, SN15 2BB, UK.

Distamine is manufactured by Chanelle Medical, Loughrea, Co. Galway, Ireland.

The information in this leaflet applies only to Distamine. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

**This leaflet was last revised in:** November 2013

**Arthritis Care**
If you need more independent information or advice, contact Arthritis Care, the UK’s largest voluntary organisation working with people with arthritis. Arthritis Care works with and for people with arthritis to promote their health, well-being and independence through services, support, self-help, influence and information.
Address: Arthritis Care, Floor 4, Linen Court, 10 East Road, London, N1 6HD
Phone: 020 7380 6500
Website: www.arthritiscare.org.uk
Freephone Helpline (10 am to 4pm Monday to Friday): 0808 8004050

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