

This product is no longer marketed in New Zealand and this consumer medicine information may not be up to date. More up-to-date consumer medicine information for a product with the same active ingredient may be available on the Medsafe website.

## PIRAM-D

Piroxicam Dispersible Tablets 10 mg and 20 mg



### What is in this leaflet

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This leaflet answers some common questions about PIRAM-D. It does not contain all the information available on this medicine. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Before prescribing PIRAM-D, your doctor will have assessed the benefits this medicine may give you against your risk of developing side effects. Your doctor may need to give you check ups and will tell you how often you need to be checked, due to your taking PIRAM-D.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may want to read it again.

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### What PIRAM-D is used for

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PIRAM-D dispersible tablets contain the active ingredient piroxicam. Piroxicam belongs to a group of medicines known as NSAIDs (Non-steroidal anti-inflammatory drugs). These medicines relieve pain and reduce inflammation.

PIRAM-D is used to relieve some symptoms caused by osteoarthritis (arthrosis, degenerative joint disease), rheumatoid arthritis and ankylosing spondylitis (rheumatism of the spine), such as swelling, stiffness and joint pain. It does not cure arthritis and will help you only as long as you continue to take it.

- Your doctor will prescribe PIRAM-D to you only when you have had unsatisfactory relief of symptoms with other non-steroidal anti-inflammatory medicines (NSAIDs).

Your doctor may have prescribed PIRAM-D for another reason. Ask your doctor if you have any questions about why PIRAM-D has been prescribed for you.

PIRAM-D is not recommended for use in children under six years of age.

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

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### Before you take PIRAM-D

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#### *When you must not take it*

**Do not take PIRAM-D if:**

- You are allergic to piroxicam or any of the other ingredients listed at the end of this leaflet
- You previously had a stomach or intestinal ulcer, bleeding or perforation.
- You currently have a stomach or intestinal ulcer, bleeding or perforation.
- You have had a history of gastrointestinal disorders (inflammation of the stomach or intestines) that predispose to bleeding disorders such as ulcerative colitis, Crohn's disease, gastrointestinal cancers, diverticulitis (inflamed or infected pouches/pockets in the colon).
- You are taking other NSAIDs, including COX-2 selective NSAIDs and acetyl-salicylic acid (aspirin), a substance present in many medicines used to relieve pain and lower fever.
- You are taking anticoagulants, such as warfarin, to prevent blood clots.
- You previously had a serious allergic reaction to piroxicam, other NSAIDs or other medications, especially skin reactions (regardless of severity) such as exfoliative dermatitis (intense reddening of skin, with skin peeling off in scales or layers), vesiculo-

bullous reactions (Stevens-Johnson syndrome, a condition with red blistered, eroded, bloody or crusted skin) and toxic epidermal necrolysis, (a disease with blistering and peeling of the top layer of skin).

- You have had severe heart failure

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are not sure if you are taking any of these medicines, ask your pharmacist.

Symptoms of an allergic reaction to PIRAM-D may include:

- Asthma, wheezing or shortness of breath
- Swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- Hives, itching or skin rash
- Fainting

**If any of the above applies to you, you should not be given PIRAM-D. Tell your doctor immediately.**

Do not take this medicine after the expiry date printed on the label or if the packaging shows signs of tampering.

### ***Before you start to take it***

Tell your doctor if:

- You have any allergies to any other medicines including aspirin or other NSAID medicines
- You have any allergies to any other substances, such as foods, preservatives or dyes
- You have or have had heartburn, indigestion, a stomach ulcer or other stomach problems
- You have bowel or intestinal problems such as ulcerative colitis
- You have been vomiting blood or bleeding from the back passage
- You have asthma
- You have kidney or liver disease
- You have high blood pressure or heart problems
- You have swelling of the ankles or feet (oedema)
- You have a tendency to bleed
- You are pregnant or planning on becoming pregnant. Like most NSAID medicines, PIRAM-D is not recommended for use during pregnancy. If there is a need to consider PIRAM-D during pregnancy, your doctor will discuss with you the benefits and risks of using it.
- You are breast-feeding or plan to breast-feed. Like most NSAID medicines, PIRAM-D is not recommended while you are breast-feeding. If there is a need to consider PIRAM-D while you are breast-feeding, your doctor will discuss with you the benefits and risks of using it.

If you have not told your doctor about any of the above, or any other medical conditions, tell him/her before you start taking PIRAM-D.

### ***Take special care with PIRAM-D***

Take special care with PIRAM-D and always tell your doctor before using PIRAM-D: like all non-steroidal anti-inflammatory drugs, PIRAM-D can cause serious reactions in the stomach and intestines, such as pain, bleeding, ulceration and perforation.

You should immediately stop taking PIRAM-D and tell your doctor if you have stomach pain, or any sign of bleeding in the stomach or intestines, such as passing black or bloodstained bowel movements, or vomiting blood.

You should immediately stop taking PIRAM-D and tell your doctor if you have any allergic reaction such as skin rash, swelling of the face, wheezing or difficulty breathing.

If you are over 70 years old, your doctor may wish to minimise treatment duration and to see you more often while you are taking PIRAM-D.

If you are over 70 years old, or you are taking other medicines like corticosteroids or certain medication for depression called selective serotonin reuptake inhibitors (SSRIs), or acetylsalicylic acid (aspirin) to prevent blood clotting, your doctor may like to prescribe you together with PIRAM-D a medicine for protecting your stomach and intestines.

You should not take this medicine if you are older than 80 years.

If you have or had any medical problems or any allergies or if you are not sure as to whether you can use piroxicam tell your doctor before using this medicine.

Make sure you have told your doctor about any other medicines that you are taking, including those that you have bought without a prescription.

### ***Taking other medicines***

Tell your doctor about any other medicines you are taking or took recently (in the last week) – even medicines you bought yourself without a prescription. Medicines can sometimes interfere with each other. It's especially important to mention to your doctor if you are taking:

- aspirin or other non-steroidal anti-inflammatory drugs for pain relief
- corticosteroids, which are medicines given to treat a variety of conditions such as allergies and hormone imbalances
- anticoagulants such as warfarin to prevent blood clots
- certain medications for depression called selective serotonin re-uptake inhibitors (SSRI)
- any medication, such as acetylsalicylic acid to prevent platelet clumping
- lithium, a medicine used to treat mood swings and some types of depression
- cimetidine, a medicine used to treat heartburn and stomach ulcers
- diuretics, also called fluid or water tablets
- medication used to treat high blood pressure
- methotrexate, a medicine used to treat arthritis and some cancers
- cyclosporin, an immuno-suppressive medicine used to prevent organ rejection
- certain antibiotics called quinolones. These are broad spectrum antibiotics used to treat infection.

If any of these apply to you tell your doctor immediately. These medicines may be affected by PIRAM-D or may affect how well PIRAM-D works. This may mean that you need different amounts of your medicines or that you need to take a different medicine. Therefore, it is important that you discuss this with your doctor or pharmacist.

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

**Ask your doctor or pharmacist if you are not sure about this list of medicines.**

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## **How to take PIRAM-D**

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Always use PIRAM-D exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

### ***How much to take***

Your doctor will give you a regular check-up to make sure you are taking the optimal dose of PIRAM-D. Your doctor will adjust your treatment to the lowest dose that best controls your

symptoms. Under no circumstances should you change the dose without first speaking to your doctor.

**Adults and the elderly:**

The maximum daily dose is 20 milligrams of PIRAM-D as one single daily dose.

If you are older than 70 years your doctor may prescribe a lower daily dose and reduce the duration of treatment.

PIRAM-D tablets can be swallowed with a glass of water, or may be dispersed in a minimum of 50 ml of water and then swallowed. PIRAM-D should be taken with or immediately after food. This may reduce the possibility of any stomach upsets.

Your doctor may prescribe PIRAM-D with another medicine to protect your stomach and intestine from potential side effects.

Do not increase the dose.

If you feel that the medicine is not very effective, always talk to your doctor.

**Children:**

The dose given in children varies depending on the child's bodyweight. Your doctor will have advised what dose is suitable.

The use of PIRAM-D is not recommended for children under 6 years of age.

***How long to take it***

As with other NSAIDs PIRAM-D will not cure your condition, but it should help to control pain, swelling and stiffness. Continue taking PIRAM-D for as long as your doctor prescribes.

***If you forget to take it:***

Take it as soon as you remember. If it is almost time for your next dose, do not take the dose you have missed, just take the next dose at the correct time. Do not double the dose.

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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

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**While you are taking PIRAM-D**

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***Things you must do***

Tell all doctors, dentists and pharmacists who are treating you that you are taking PIRAM-D.

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are currently taking PIRAM-D

If you become pregnant while taking PIRAM-D tell your doctor immediately.

If you plan to have surgery, including dental surgery, tell your doctor (including surgeon and/or anaesthetist) or dentist that you are taking PIRAM-D.

If you get an infection while taking PIRAM-D, tell your doctor. PIRAM-D may hide some of the signs of an infection and may make you think, mistakenly, that you are better or that it is not serious.

Keep all appointments you and your doctor have scheduled so that your progress can be followed.

### ***Things you must not do***

Do not stop taking PIRAM-D or change the dose without first checking with your doctor.

Do not use PIRAM-D to treat any other complaints unless your doctor tells you to.

Do not give PIRAM-D to anyone else, even if they have the same condition as you.

### ***Things to be careful of***

PIRAM-D may cause dizziness or light-headedness in some people. Make sure you know how you react to PIRAM-D before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

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## **Side effects**

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

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Check with your doctor as soon as possible if you have any problems while taking PIRAM-D, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

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:**

- Stomach upset, including nausea (feeling sick), vomiting, heartburn, indigestion or cramps
- Constipation, diarrhoea, stomach pain or wind
- Loss of appetite
- Dizziness, sleepiness or drowsiness
- Sleeplessness, nightmares
- Change in mood, for example, depression, restlessness or irritability
- Headache
- Buzzing or ringing in the ears
- Hair loss or thinning
- Loose nails
- Sore mouth or tongue.

These side effects are usually mild.

### **Tell your doctor immediately if you notice any of the following:**

- Severe pain or tenderness in the stomach
- Eye problems such as blurred vision, sore red eyes, itching
- Severe dizziness, spinning sensation
- Severe or persistent headache

- Tingling or numbness of the hands or feet
- Fast or irregular heartbeat
- Difficulty hearing, deafness
- Bruising or bleeding more easily, reddish or purple blotches under the skin
- Signs of anaemia such as tiredness, being short of breath and looking pale
- A change in the colour of urine or blood in the urine
- A change in the amount or frequency of urine passed, burning feeling when passing urine
- Yellowing of the skin and eyes (jaundice)
- Severe upper stomach pain, often with nausea and vomiting
- Unusual weight gain, swelling of the ankles or legs
- Symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

**If any of the following happen, stop taking PIRAM-D and tell your doctor immediately or go to the accident and emergency department at your nearest hospital:**

- Vomiting blood or material that looks like coffee grounds
- Bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- Swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- Asthma, wheezing, shortness of breath
- Sudden or severe itching, skin rash, hives
- Pain or tightness in the chest

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don't understand anything in this list.

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## **In case of overdose**

**Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Accident and Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any PIRAM-D by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.** Take the container of PIRAM-D with you if you can.

**Keep telephone numbers for these places handy.**

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## **Storage conditions**

Keep your PIRAM-D tablets in the container until it is time to take them. If you take the tablets out of the bottle they will not keep well.

Keep your PIRAM-D tablets in a cool dry place where the temperature stays below 30°C. Do not store PIRAM-D or any other medicine in the bathroom or near a sink. Avoid exposing your PIRAM-D tablets to heat, light and moisture. Keep out of reach of children.

## ***Disposal***

If your doctor tells you to stop taking PIRAM-D or if the tablets have passed their expiry date, ask your pharmacist what to do with any that are leftover.

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## **Product Description**

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### ***What PIRAM-D dispersible tablets look like***

PIRAM-D 10 mg tablets are white, round tablets, marked "PX/10" on one side and "G" on the other side.

PIRAM-D 20 mg tablets are white, capsule shaped tablets, marked "PX/20" on one side and "G" on the other side.

Each PIRAM-D dispersible tablet contains the active ingredient piroxicam.

Each PIRAM-D dispersible tablet also contains lactose, microcrystalline cellulose, hydroxypropyl cellulose and sodium stearyl fumarate.

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## **If you want to know more**

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Should you have any questions regarding this product, please contact your doctor or pharmacist.

### ***Who supplies this medicine***

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland.

Telephone: (09) 579 2792

### ***Date of information***

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