

MOBILIS & MOBILIS D

piroxicam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MOBILIS and MOBILIS D (hereafter referred to as MOBILIS). It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What MOBILIS is used for

MOBILIS treats the symptoms of:

- rheumatoid arthritis
- osteoarthritis
- ankylosing spondylitis, a chronic inflammatory rheumatic disorder that primarily affects, but is not limited to the spine

Although MOBILIS can relieve the symptoms of pain and inflammation, it will not cure your condition.

MOBILIS belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines work by relieving pain and inflammation (heat, throbbing, swelling and redness).

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you take MOBILIS

When you must not take it

Do not take MOBILIS if you have an allergy to:

- any medicine containing piroxicam
- any of the ingredients listed at the end of this leaflet
- any other medicine that is also an NSAID, including aspirin

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or are NSAID medicines.

Some of the symptoms of an allergic reaction may include:

- asthma, shortness of breath, wheezing or difficulty breathing
- nasal polyps (growths inside the nose)
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

If you are allergic to NSAID medicines and take MOBILIS, these symptoms may be severe.

Do not take this medicine if:

- **you are pregnant or plan to become pregnant**
Like most NSAID medicines, MOBILIS is not recommended for use during pregnancy. It may affect your developing baby if you take it while you

are pregnant, especially during the last three months of pregnancy.

NSAIDs have been associated with reversible infertility in some women. The use of NSAIDs in early pregnancy can increase the risk of spontaneous abortion.

Your doctor will discuss the risks and benefits of taking this medicine during pregnancy.

- **you have a peptic ulcer (i.e. a stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before**
- **you are vomiting blood, or material that looks like coffee grounds, or if this has happened to you recently**
- **you are bleeding from the rectum (back passage), have black sticky bowel motions (stools), or bloody diarrhoea, or if this has happened to you recently.**
- **you have, or have had inflammation of the lining of the stomach or bowel**
Some examples of these conditions include Crohn's disease and ulcerative colitis
- **you have severe liver disease**
- **you have severe kidney disease**

Do not give this medicine to children under the age of 12.

The safety and effectiveness of MOBILIS in this age group have not been established.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

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 any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heartburn, indigestion, stomach ulcers or other stomach problems
- bowel or intestinal problems
- asthma
- kidney or liver disease
- heart failure
- high blood pressure or heart problems
- swelling of the ankles or feet (oedema)
- a tendency to bleed

Tell your doctor if you are breast-feeding or plan to breast-feed.

Your doctor can discuss with you the risks and benefits involved.

Like most NSAID medicines, the active ingredient in MOBILIS passes into breast milk and may affect your baby.

Tell your doctor if you currently have an infection.

If you take MOBILIS while you have an infection, it may hide some of the signs of an infection (e.g. pain, fever, swelling or redness). This may make you think, mistakenly, that you are better or that it is not serious.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and MOBILIS may interfere with each other. These include:

- aspirin (including low doses used to prevent your blood from clotting in certain heart conditions), salicylates or other NSAIDs
- warfarin or similar medicines that are used to stop blood clots
- digoxin or digitoxin, medicines used to treat heart failure
- medicines used to treat diabetes
- certain antibiotics called sulfonamides
- phenytoin, a medicine used to treat epilepsy
- lithium, a medicine used to treat some types of depression
- selective serotonin reuptake inhibitors, medicines used to treat depression
- corticosteroids, medicines used to suppress the immune system or reduce inflammation
- methotrexate, a medicine used to treat arthritis and some cancers
- diuretics, also called fluid or water tablets
- medicines used to treat high blood pressure
- colestyramine, a medicine used to reduce cholesterol
- alcohol

These medicines may be affected by MOBILIS or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take MOBILIS

Follow all directions given to you by your doctor or 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 for help.

How much to take

The usual dose is between 10 mg and 20 mg, taken as a single dose each day.

However, depending on your condition and how you react to the medicine, your doctor may ask you to take a different dose.

How to take it

Capsules

Swallow the capsule whole with a glass of water.

Dispersible Tablets

The dispersible tablet should be dissolved in a glass of water and drunk straight away.

When to take it

Take your medicine immediately after food to avoid the chance of an upset stomach.

Try to take your medicine at the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to relieve pain and inflammation but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is less than 3 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

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

You may need urgent medical attention.

If you take too much MOBILIS, you may feel sick or have stomach pain, vomit, headache, dizziness, drowsiness and confusion.

While you are taking MOBILIS

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MOBILIS.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon that you are taking this medicine. MOBILIS can slow down blood clotting.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you get an infection while taking this medicine, tell your doctor immediately. MOBILIS may hide some of the signs of an infection (e.g. pain, fever, redness, swelling). You may think, mistakenly, that you are better or that the infection is not serious.

Things you must not do

Do not take MOBILIS to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how MOBILIS affects you.

As with other NSAID medicines, MOBILIS may cause dizziness, drowsiness or blurred vision in some people.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful of ingesting alcohol whilst taking MOBILIS.

As with other NSAID medicines, ingesting alcohol may increase your risk of developing stomach problems.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MOBILIS.

This medicine helps most people but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age, you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps
- loss of appetite
- constipation, diarrhoea, stomach pain, wind
- dizziness, light-headedness
- drowsiness, sleepiness
- headache
- buzzing or ringing in the ears
- sore mouth or tongue
- hair loss or thinning
- loose nails
- change in mood, for example depression

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- severe pain or tenderness in the stomach
- visual disturbances such as blurred vision
- severe dizziness, spinning sensation
- fast or irregular heartbeat, also called palpitations
- difficulty hearing, deafness
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish or purple blotches under the skin
- signs of anaemia such as tiredness, being short of breath and looking pale
- yellowing of the eyes or skin, also called jaundice

- 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
- fever, cough, sore throat, feeling generally unwell, skin rash (in some instances it can develop over 2 to 7 days), rashes can be painful and itchy, blistering or peeling of the skin, facial swelling, sore/red eyes or lips, in some instances reactions can be delayed by up to 3 or 4 weeks.

The above list includes serious side effects that may need urgent medical attention.

If any of the following happen, stop taking MOBILIS and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- vomiting blood or material that looks like coffee grounds
- bleeding from your back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea
- swelling of the face, lips or tongue which may make swallowing or breathing difficult
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives
- fainting
- 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.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

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

After taking MOBILIS

Storage

Keep your medicine tablets in the pack until it is time to take them.

If you take them out of the pack, they may not keep well.

Keep MOBILIS capsules in a cool dry place where the temperature stays below 30°C.

Keep MOBILIS D dispersible tablets in a cool dry place where the temperature stays below 25°C.

Do not store MOBILIS or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach them.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine, or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

MOBILIS is available as capsules or dispersible tablets.

Capsules

- MOBILIS 10 - brown and ivory capsule marked PM 10 and a Greek alpha symbol
- MOBILIS 20 - light grey capsule marked PM 20 and a Greek alpha symbol

The capsules are available in packs of 50.

Dispersible Tablets

- MOBILIS D-10 - white to slightly yellow flat bevel edged tablet, approximately 10 mm in diameter, blank on one side and breakline on reverse
- MOBILIS D-20 - white to slightly yellow capsule shaped tablets, 17mm x 6mm, with a breakline on one side and blank on the reverse

The dispersible tablets are available in packs of 25.

Ingredients

MOBILIS capsules and dispersible tablets contain 10 mg or 20 mg of piroxicam as the active ingredient.

Capsules

The capsules also contain the following inactive ingredients:

- lactose monohydrate
- maize starch
- sodium starch glycollate
- sodium lauryl sulfate
- magnesium stearate
- iron oxide black (E172)
- titanium dioxide (E171)
- colloidal anhydrous silica
- gelatin
- shellac
- propylene glycol
- ammonium hydroxide
- potassium hydroxide
- iron oxide yellow (E172) [10 mg capsule only]
- iron oxide red (E172) [10 mg capsule only]

The capsules are gluten free.

Dispersible Tablets

The dispersible tablets also contain the following inactive ingredients:

- lactose monohydrate
- microcrystalline cellulose
- hydroxypropylcellulose
- sodium stearyl fumarate

The tablets are gluten free.

Supplier

Mobilis is supplied by:

Alphapharm Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

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