

Mobilis

contains the active ingredient piroxicam

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about 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 benefits and risks. Your doctor has weighed the risks of you taking Mobilis against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Mobilis is used for

Mobilis is used to treat the symptoms of:

- * rheumatoid arthritis
- * osteoarthritis
- * ankylosing spondylitis.

Mobilis belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by relieving pain and inflammation.

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

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

Your doctor, however, may have prescribed Mobilis for another reason.

Mobilis is available only with a doctor's prescription.

There is no evidence that Mobilis is addictive.

When you must not take it

Do not take Mobilis if you have an allergy to:

- * medicines containing piroxicam or any other NSAID medicine
- * aspirin
- * any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to these medicines may include:

- * asthma, wheezing or shortness of breath
- * nasal polyps (growths in the nose)
- * swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- * hives, itching or skin rash
- * fainting.

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

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.

Do not take Mobilis if you:

- * have, or have had a peptic ulcer (ulcer of the stomach or duodenum)
- * have, or have had inflammation of the lining of the stomach or bowel (e.g. Crohn's disease and ulcerative colitis)
- * have, or have had severe allergic reactions of any type, especially reactions to the skin
- * have, or have had severe heart failure
- * are vomiting blood or material that looks like coffee grounds
- * are bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea.

Do not give Mobilis to children under 12 years of age.

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

Do not take Mobilis if the packaging shows signs of tampering or does not look quite right.

Do not take Mobilis if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have allergies to:

- * any other medicines including aspirin or other NSAID medicines
- * any other substances such as foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Like most NSAID medicines, Mobilis is not recommended for use during pregnancy, as it may affect your developing baby. If there is a need to consider Mobilis during your pregnancy, your doctor will discuss the risks and benefits of taking it.

Talk to your doctor about taking Mobilis if you are over the age of 70 years.

The use of Mobilis in patients aged over 70 years may be associated with a high risk of complications. Your doctor will discuss the risks and benefits of taking Mobilis above this age.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Mobilis passes into breast milk. Therefore, there is a possibility that the breastfed baby may be affected. Your doctor will discuss the risks and benefits of taking Mobilis when breastfeeding.

Tell your doctor if you have, or have ever had, any other health problems or medical conditions, including:

- * heartburn, indigestion, stomach ulcer or other stomach problems
- * asthma
- * allergic reactions, especially those affecting the skin
- * kidney or liver disease
- * severe dehydration
- * high blood pressure or heart problems, including heart failure
- * swelling of the ankles or feet (oedema)
- * a tendency to bleed.

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 the infection (such as pain, fever, swelling or redness). This may make you mistakenly think that you are better or that your infection is not serious.

Your doctor may want to take special care if you have any of these conditions.

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

Taking other medicines

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

Some medicines may be affected by Mobilis, or may affect how well it works. The combination of Mobilis and the following medicines may cause or worsen certain medical conditions.

These include:

- * aspirin, salicylates or other NSAID medicines or a group of medicines called coxibs also used to relieve pain, swelling and other symptoms of inflammation.
- * fluid tablets, also called diuretics, particularly thiazide diuretics
- * medicines used to treat high blood pressure or heart conditions, these include a group of medicines called ACE inhibitors or angiotensin receptor blockers and betablockers
- * medicines used to prevent blood clots such as warfarin
- * selective serotonin reuptake inhibitors, a group of medicines used to treat depression
- * acetylsalicylic acid, a medicine used to treat thrombotic cerebrovascular and cardiovascular disease

- * digoxin, a medicine used to treat congestive heart failure
- * cyclosporine, tacrolimus and other immunosuppressants used to minimize rejection of organ transplants
- * sulfonylureas, a group of medicines used to treat diabetes
- * sulfonamide antibiotics
- * methotrexate, a medicine used to treat arthritis and some cancers
- * lithium, a medicine used to treat mood swings and some types of depression
- * oral corticosteroids, a group of medicines used to reduce inflammation in the body
- * phenytoin, a medicine used to treat epilepsy.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take Mobilis

Follow all directions given to you by your doctor and 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.

How much to take

The dose varies from person to person.

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

Please refer to section "How to take it" (Dispersible tablets). This contains important information on how to use these types of tablets.

How to take it

Capsules:

Swallow whole with a glass of water.

Dispersible tablets:

Tablets should be used whole.

Do not split tablets into halves and use individual halves.

Dissolve in a glass of water, then drink it straight away.

When to take it

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

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

Keep taking Mobilis for as long as your doctor tells you to.

This medicine will not cure your condition but it should help to control pain, swelling and stiffness.

If you have arthritis, you may have to take Mobilis every day on a long-term basis.

If you forget to take it

If it is almost time for 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 you missed.

If you miss more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or 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 experience mild symptoms of lethargy, drowsiness, fever, increased heart rate and stomach upset.

While you are taking Mobilis

Things you must do

Tell your doctor immediately if you become pregnant or if you experience an allergic reaction while taking Mobilis.

If you are about to start taking a new medicine, tell your doctor or pharmacist that you are taking Mobilis.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Mobilis.

If you are going to have surgery, including dental surgery, tell your doctor or dentist that you are taking Mobilis.

Mobilis can slow down blood clotting.

If you get an infection while taking Mobilis, tell your doctor.

Mobilis may hide some of the signs of an infection (such as pain, fever, redness, swelling). You may mistakenly think that you are better or that your infection is not serious.

Things you must not do

Do not use Mobilis to treat any other conditions unless advised by your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

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 this occurs, do not drive, operate machinery or do anything else that could be dangerous.

Report any side effects to your doctor promptly.

If you are over 70 years of age, you may have an increased chance of getting side effects.

Side effects

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

Mobilis helps most people with arthritis and ankylosing spondylitis, but it may have unwanted side effects in some people.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

Tell your doctor if you experience any of the following and they worry you:

- * stomach upset including nausea (feeling sick), vomiting, indigestion
- * constipation, diarrhoea, stomach pain, wind
- * loss of appetite
- * dizziness, sleepiness, drowsiness
- * headache
- * buzzing or ringing in the ears
- * hair loss or thinning
- * loose nails
- * sore mouth or tongue.

The above side effects are usually mild.

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

- * severe pain or tenderness in the stomach
- * first signs of a mouth ulcer
- * eye problems such as blurred vision, sore red eyes, itching
- * severe dizziness, spinning sensation
- * fast or irregular heart beat
- * difficulty hearing, deafness
- * unusual bruising or bleeding, reddish or purple blotches under the skin
- * signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- * 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
- * an increase or decrease in the amount of urine passed, burning feeling when passing urine
- * yellowing of the eyes or skin (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.

The side effects listed above are serious. You may need urgent medical attention.

Stop taking Mobilis and tell your doctor immediately or go to Accident and Emergency at the nearest hospital if any of the following happen:

- * vomiting blood or material that looks like coffee grounds
- * first appearance of a skin rash or any other signs of hypersensitivity
- * bleeding from your back passage (rectum), black sticky 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
- * fainting, seizures or fits
- * pain or tightness in the chest.

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

Tell your doctor if you notice anything that is making you feel unwell while you are taking, or soon after you have finished taking Mobilis, even if it is not on this list.

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

After taking Mobilis

Storage

Keep Mobilis where children cannot reach it.

Keep Mobilis in a cool dry place.

Mobilis capsules should be stored in a place where the temperature stays below 30 degrees C.

Mobilis dispersible 10mg tablets and Mobilis dispersible 20mg tablets should be stored in a place where the temperature stays below

25 degrees C.

Do not keep Mobilis or any other medicine in the bathroom or near a sink. Do not leave Mobilis in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Mobilis, or your medicine has passed its expiry date, ask your pharmacist what to do with any capsules or tablets that are left over.

Product description

What it looks like

Mobilis is available as capsules or dispersible tablets.

Mobilis CAPSULES come in two strengths:

- * 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.

Mobilis TABLETS come in two strengths:

- * Mobilis D-10 - white flat bevel edged tablet, approximately 10mm in diameter, blank on one side and breakline on reverse.
- * Mobilis D-20 - White capsule shaped tablets, 17mm x 6mm, with a breakline on one side and blank on the reverse.

Tablets should be used whole.

Do not split tablets into halves and use individual halves.

Mobilis 10 capsules and Mobilis D-10 tablets come in packs of 50.

Mobilis 20 capsules and Mobilis D-20 tablets come in packs of 25.

Ingredients

The active ingredient in Mobilis capsules and tablets is piroxicam.

CAPSULES

Each Mobilis 10 capsule contains 10 mg of piroxicam.

Each Mobilis 20 capsule contains 20 mg of piroxicam.

The capsules also contain the following inactive ingredients:

- * lactose
- * 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.

TABLETS

Each Mobilis D-10 tablet contains 10 mg of piroxicam.

Each Mobilis D-20 tablet contains 20 mg of piroxicam.

The tablets also contain the following inactive ingredients:

- * lactose
- * microcrystalline cellulose
- * hydroxypropylcellulose
- * sodium stearyl fumarate.

The tablets are gluten free.

Supplier

Mobilis is supplied by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Mobilis 10: AUST R 52201

Mobilis 20: AUST R 52202

Mobilis D-10: AUST R 53282

Mobilis D-20: AUST R 53284

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