

MOBILIS® & MOBILIS® D

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking MOBILIS?

MOBILIS contains the active ingredient piroxicam. MOBILIS is used to treat the symptoms of rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis, a chronic inflammatory rheumatic disorder that primarily affects, but is not limited to the spine. For more information, see Section [1. Why am I taking MOBILIS?](#) in the full CMI.

2. What should I know before I take MOBILIS?

Do not take if you have ever had an allergic reaction to MOBILIS, if you have any active inflammatory disease or ulcers, if you have kidney, liver or heart problems, any other medicine containing piroxicam, any COX-2 inhibitor, aspirin or NSAID medicines or any of the ingredients listed at the end of the CMI. Do not take MOBILIS if you are pregnant in your third trimester of pregnancy, or you are breastfeeding. If you are pregnant

in any stage, please speak to your doctor first about this medicine.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I take MOBILIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MOBILIS and affect how it works. Examples of such medicines include aspirin or other NSAIDs, warfarin, digoxin, medicine for diabetes or epilepsy or depression, certain antibiotics, diuretics, medicine for blood pressure or cholesterol and alcohol. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take MOBILIS?

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 some other dose.

More instructions can be found in Section [4. How do I take MOBILIS?](#) in the full CMI.

5. What should I know while taking MOBILIS?

Things you should do	<ul style="list-style-type: none">• If you become pregnant while taking MOBILIS, tell your doctor immediately.• If you get an infection while taking MOBILIS, tell your doctor immediately.• Tell all doctors, dentists or pharmacists who are treating you that you are taking MOBILIS.
Things you should not do	<ul style="list-style-type: none">• Do not give MOBILIS to anyone else, even if they have the same condition as you.• Do not take MOBILIS to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• 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.
Drinking alcohol	<ul style="list-style-type: none"> Alcohol may interfere with MOBILIS and may affect how well it works. Ask your doctor or pharmacist for more information.
Looking after your medicine	<ul style="list-style-type: none"> Keep them in a cool dry place (store below 30°C for capsules and store below 25°C for tablets). Keep your capsules or tablets where young children cannot reach them.

For more information, see Section [5. What should I know while taking MOBILIS?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Some of the common side effects are upset stomach (nausea or vomiting, cramps), diarrhoea or constipation, dizziness or lightheaded-ness, headache. Some side effects may be serious and need medical attention. If you experience serious allergic reaction, vomiting blood or see blood in stool, fainting or chest tightness/pain, go to Emergency

at your nearest hospital immediately. If you are over 65 years of age, you may have an increased chance of getting side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

MOBILIS® & MOBILIS® D

Active ingredient(s): *Piroxicam*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking MOBILIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking MOBILIS.**

Where to find information in this leaflet:

- [1. Why am I taking MOBILIS?](#)
- [2. What should I know before I take MOBILIS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take MOBILIS?](#)
- [5. What should I know while taking MOBILIS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking MOBILIS?

MOBILIS contains the active ingredient piroxicam. 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, redness).

MOBILIS is used to treat the symptoms of rheumatoid arthritis, osteoarthritis and 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.

Your doctor may have prescribed MOBILIS for another reason.

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

2. What should I know before I take MOBILIS?

Warnings

Do not take MOBILIS if:

- you are allergic or hypersensitive to:
 - piroxicam (the active ingredient in MOBILIS), or any of the ingredients listed at the end of this leaflet (see Product Description), or other medicines containing piroxicam
 - aspirin
 - any other medicine that is also an NSAID

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

- you are taking aspirin or any other medicine that is also an NSAID
- you have had a severe allergic reaction to any medicine in the past, especially skin reactions
- you have had a skin reaction to piroxicam in the past
- you have a gastric ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had gastric ulcers before
- you have or have had inflammation and/or ulceration of the lining of the stomach or bowel.

Some examples of these conditions are Crohn's disease and ulcerative colitis

- you have severe kidney disease
- you have severe heart failure
- you have severe liver failure
- you are about to have or have had recent coronary artery bypass surgery
- you are in your third trimester of pregnancy or are breastfeeding

Do not give MOBILIS to children of 12 years and under.

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

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

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.

Check with your doctor if you:

- have allergies to any other medicines (including aspirin or other NSAID medicines), foods, preservatives or dyes.
- have or have had any of the following conditions:
 - heartburn, indigestion, stomach ulcers or other stomach problems
 - bowel or intestinal problems
 - asthma
 - kidney or liver disease
 - heart failure
 - heart disease
 - Use of MOBILIS may increase your risk of developing a heart condition such as heart attack even if you don't have a history of heart disease.
 - high blood pressure
 - swelling of the ankles or feet (oedema)
 - a tendency to bleed.

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). You may think, mistakenly, that you are better or that the infection is not serious.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take MOBILIS if you are pregnant, or intend on becoming pregnant, unless your doctor says otherwise.

MOBILIS is not to be taken at all during the third trimester of pregnancy.

MOBILIS should not be taken during the first two trimesters of pregnancy unless the expected benefits to the mother outweigh the risks to the baby. Seek advice from your doctor.

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 MOBILIS during pregnancy.

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

MOBILIS is not to be taken during breastfeeding.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with MOBILIS and affect how it works. 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
- ciclosporin and tacrolimus, medicines used to suppress the immune system
- 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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MOBILIS.

4. How do I take MOBILIS?

How much to take

- The usual dose is between 10 mg and 20 mg, taken as a single dose each day.
- Follow the instructions provided and take MOBILIS until your doctor tells you to stop.

When and how long to take MOBILIS

- Try to take it at the same time each day, either morning or evening.
- It is best to take your medicine immediately after food to avoid the chance of an upset stomach.

If you need to take MOBILIS for a long time, see your doctor for regular check-ups so that he/she can monitor your condition and treatment.

How to take MOBILIS

Capsules

Swallow the capsule whole with a glass of water.

Dispersible Tablets

Allow the dispersible tablet to dissolve in a glass of water and then drink it straight away.

If you forget to take MOBILIS

MOBILIS should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your medicine as you would normally.

If it is almost time for your next dose (e.g. within 2 or 3 hours), skip the dose you missed and take your next dose when you are meant to.

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

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

If you take too much MOBILIS

If you take too much MOBILIS, you may feel sick or have stomach pain, vomiting, headache, dizziness, drowsiness and confusion. You may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking MOBILIS?

Things you should do

- If you become pregnant while taking MOBILIS, tell your doctor immediately.
- 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 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 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 should 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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 if you are not alert.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful of drinking alcohol whilst taking MOBILIS. As with other NSAID medicines, ingesting alcohol may increase your risk of developing stomach problems.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not take this medicine after the expiry date.

Keep it where young children cannot reach it.

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

When to discard your medicine

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.

6. Are there any side effects?

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

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
<ul style="list-style-type: none">● 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	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Call your doctor immediately:</p> <ul style="list-style-type: none">• severe pain or tenderness in the stomach• visual disturbances such as blurred vision• severe dizziness, spinning sensation• increase in blood pressure• 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	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 <p>Seek Emergency medical attention:</p> <ul style="list-style-type: none"> ● 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 	

Serious side effects	What to do
<p>make swallowing or breathing difficult</p> <ul style="list-style-type: none"> ● asthma, wheezing, shortness of breath ● sudden or severe itching, skin rash, hives ● fainting ● pain or tightness in the chest. 	

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What MOBILIS contains

Active ingredient (main ingredient)	Piroxicam (10 mg or 20 mg)
Other ingredients (inactive ingredients)	MOBILIS capsules also contain: <ul style="list-style-type: none">• lactose monohydrate• maize starch• sodium starch glycollate• sodium lauryl sulfate• magnesium stearate• iron oxide black• titanium dioxide• colloidal anhydrous silica• gelatin• shellac• propylene glycol• ammonium hydroxide• potassium hydroxide• iron oxide yellow [10 mg only]

	<ul style="list-style-type: none"> • iron oxide red [10 mg only] <p>MOBILIS D dispersible tablets also contain:</p> <ul style="list-style-type: none"> • lactose monohydrate • microcrystalline cellulose • hydroxypropylcellulose • sodium stearyl fumarate
Potential allergens	Sugars as lactose and trace quantities of saccharin. The capsules also contain trace quantities of sulfites.

Do not take this medicine if you are allergic to any of these ingredients.

What MOBILIS looks like

MOBILIS is available as capsules or dispersible tablets.

Capsules

- MOBILIS 10 - size 2 capsule with brown opaque cap and ivory opaque body printed in black "PM10" on the body and "α" on the cap (AUST R 52201). Available in packs of 50.
- MOBILIS 20 - size 2 capsule with light grey opaque cap and body printed in black "PM20" on the body and

" α " on the cap (AUST R 52202). Available in packs of 25.

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 (AUST R 53282). Available in packs of 50.
- MOBILIS D-20 - white to slightly yellow capsule shaped tablets, 17 mm x 6 mm, with a breakline on one side and blank on the reverse (AUST R 53284). Available in packs of 25.

Some strengths, pack sizes and/or pack types may not be marketed.

Who distributes MOBILIS

Alphapharm Pty Ltd trading as Viatris

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