

APX-Meloxicam

Tablets

Meloxicam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about APX-Meloxicam.

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 APX-Meloxicam against the benefits they expect it will have for you.

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

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

Keep this leaflet with the medicine.

You may need to read it again.

What APX-Meloxicam is used for

APX-Meloxicam is used to treat the symptoms of:

- osteoarthritis
- rheumatoid arthritis.

Both diseases mainly affect the joints causing pain and swelling.

Although APX-Meloxicam can relieve the symptoms of pain and

inflammation, it will not cure your condition. APX-Meloxicam belongs to a family of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

These medicines work by relieving pain and inflammation.

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.

- have a disease of the heart with shortness of breath, and swelling of the feet or lips due to fluid build-up
- experience bleeding from the stomach, gut or any other bleeding
- had a stroke resulting from a bleed in the brain or have a bleeding disorder
- have a galactose intolerance
- have a peptic (stomach) ulcer
- have or have had inflammation of the lining of the stomach or bowel (e.g. Crohn's Disease or Ulcerative Colitis)
- have severe liver or kidney problems
- are currently taking the following medicines: fluconazole (used to treat fungal infections) or certain sulfur antibiotics (e.g. sulfamethoxazole).

Do not take this medicine if you are pregnant, or think you may be pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in APX-Meloxicam passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine/ it to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Before you take APX-Meloxicam

When you must not take it

Do not take APX-Meloxicam if you have an allergy to:

- any medicine containing meloxicam
- any of the ingredients listed at the end of this leaflet
- aspirin or any other NSAIDs.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take APX-Meloxicam if you:

- are about to undergo a coronary artery bypass graft surgery

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

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

- high blood pressure or fluid retention
- diabetes
- high cholesterol
- heartburn, indigestion, ulcers or other stomach problems
- kidney or liver disease
- asthma or any other breathing problems.

Tell your doctor you are using an IUD (intrauterine device) for birth control.

NSAID medicines, like APX-Meloxicam, may decrease the effectiveness of IUDs.

Tell your doctor if you currently have an infection.

APX-Meloxicam may hide some of the signs of an infection. This may make you think, mistakenly, that you are better or that it is not serious.

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

Taking other medicines

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

Some medicines and APX-Meloxicam may interfere with each other. These include:

- aspirin, salicylates or other NSAIDs
- medicines used to thin your blood (e.g. warfarin, heparin and ticlopidine)
- medicines used to treat high blood pressure and other heart problems (e.g. ACE inhibitors, angiotensin receptor antagonists and diuretics, also called fluid or water tablets)

When taken together these medicines can cause kidney problems.

- lithium, a medicine used to treat some types of depression
- antidepressants called selective serotonin reuptake inhibitors (SSRIs)
- methotrexate, a medicine used to treat rheumatoid arthritis and some types of cancer
- cyclosporin, a medicine used to treat rheumatoid arthritis and certain problems with the immune system
- terfenadine and astemizole, medicines used to prevent or relieve the symptoms of allergy, such as hay fever or insect stings
- medicines to treat diabetes
- colestyramine, a medicine used to treat high cholesterol levels in the blood
- corticosteroids, medicines usually used to treat inflammatory conditions, such as skin rashes and asthma
- some medicines used to treat infections (e.g. erythromycin, sulfur antibiotics, ketoconazole, itraconazole)
- some medicines used to treat irregular heartbeats (e.g. amiodarone and quinidine)
- pemetrexed, a medicine used in the treatment of certain lung cancers.

These medicines may be affected by APX-Meloxicam or may affect how

well it works. You may need different amounts of your medicines, or you may need different medicines.

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

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

For the treatment of osteoarthritis

The usual dose of APX-Meloxicam is 7.5 mg, taken as a single dose each day.

Depending on the severity of your condition and your response to treatment, your doctor may increase this dose to 15 mg taken as a single dose each day.

For the treatment of rheumatoid arthritis

The usual dose of APX-Meloxicam is 15 mg taken as a single dose each day.

Depending on your response, your doctor may reduce this dose to 7.5 mg taken as a single dose each day.

The maximum recommended daily dose of APX-Meloxicam is 15 mg.

For patients with kidney problems undergoing dialysis, the maximum recommended daily dose is 7.5 mg.

Ask your doctor for more information if you have been advised to take a different dose.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about 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.

Take your medicine with or straight after food.

This may help reduce the possibility of stomach upset.

How long to take it

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

This medicine helps control your condition, 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 almost time for your next dose (e.g. within 2-3 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, then go back to taking it 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 Emergency at your nearest hospital if you think that you or anyone else may have taken too much APX-Meloxicam. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- nausea and/or vomiting

- headache
- drowsiness and/or dizziness
- blurred vision
- fits or seizures
- low blood pressure
- difficulty in breathing
- impaired consciousness
- kidney failure.

Things to be careful of

Be careful driving or operating machinery until you know how APX-Meloxicam affects you.

This medicine 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.

Side effects

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

This medicine helps most people but it may have unwanted side effects in a few people. All medicines 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.

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

Not all of these side effects have been reported with APX-Meloxicam but have been seen with similar medicines.

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, vomiting, heartburn, indigestion, belching, cramps or pain
- headache
- flu-like symptoms, runny or blocked nose, cough, sore mouth or throat, discomfort when swallowing
- constipation, diarrhoea or wind
- dizziness or light-headedness
- skin rashes, which may be caused by exposure to sunlight, can blister and may take on the

- appearance of a severe burn, or itching
- increase in blood pressure
- tinnitus (ringing in the ear).

The above list includes the more common side effects of your medicine. These side effects are usually mild.

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

- blurred vision
- any change in the amount or colour of your urine (red or brown) or any pain or difficulty experienced when urinating
- collapse or fainting, shortness of breath or tiredness, fast or irregular heartbeat, chest pain, swollen or sore leg veins
- severe dizziness
- severe pain or tenderness in the stomach
- flaking of the skin
- yellowing of the skin and eyes (known as jaundice)
- swelling of your ankles, legs or other parts of your body
- signs of anaemia (such as: tiredness, being short of breath and looking pale)
- irritation of your mucous membranes (e.g. lips, mouth, eyes or genitals).

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

If any of the following happen, tell your doctor immediately or go to Emergency at your nearest hospital:

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

- sudden or severe itching, skin rash or hives
- weakness in one part or side of your body, slurred speech, blurred vision or visual disturbances.

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

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

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

Product description

What it looks like

APX-Meloxicam is the brand name of your medicine. It is available as tablets in two strengths.

- APX-Meloxicam 7.5 mg tablets - Light yellow, round, uncoated tablet with score line between 'F' and '1' debossed on one side and plain on the other side. Available in blister packs of 30 and 60's * tablets.
- APX-Meloxicam 15 mg tablets - Light yellow, round, uncoated tablet with score line between 'F' and '2' debossed on one side and plain on the other side. Available in blister packs of 30 and 60* tablets.

*Not distributed in Australia.

Ingredients

Active ingredient:

- APX-Meloxicam 7.5mg tablet 7.5mg of meloxicam.
- APX-Meloxicam 15mg tablet 15mg of meloxicam.

Inactive ingredients:

APX-Meloxicam also contain:

- sodium citrate
- lactose monohydrate
- microcrystalline cellulose
- povidone
- crospovidone
- colloidal anhydrous silica
- magnesium stearate.

This medicine contains lactose.

Supplier

APX-Meloxicam is supplied in Australia by:

Arrow Pharma Pty Ltd
15- 17 Chapel St
Cremorne VIC 3121
Ph: 1800 195 055

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*Australian Registration
Number(s)*

APX-Meloxicam 7.5 mg tablets:
AUST R 289713.

APX-Meloxicam 15 mg tablets:
AUST R 289714