

Moxicam

Capsules

contains the active ingredient meloxicam

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Moxicam.

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 Moxicam 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 Moxicam is used for

Moxicam is used to treat the symptoms of osteoarthritis and rheumatoid arthritis. Both of these diseases mainly affect the joints causing pain and swelling.

Although Moxicam can relieve symptoms such as pain and inflammation, it will not cure your condition.

Moxicam 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 why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

It is available only with a doctor's prescription.

Before you take Moxicam

When you must not take it

Do not take Moxicam if you have an allergy to:

- any medicine containing meloxicam (the active ingredient)

- any of the other ingredients listed at the end of this leaflet. This includes rare inherited conditions of galactose intolerance.
- aspirin or any other NSAID medicine.

Some of the symptoms of an allergic reaction may include:

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

Do not take Moxicam if:

- you are about to undergo coronary artery bypass graft surgery
- you have a disease of the heart with shortness of breath, and swelling of the feet or lips due to fluid build-up
- you experience bleeding from the stomach, gut or any other bleeding
- you have had a stroke resulting from a bleed in the brain or have a bleeding disorder
- have a galactose intolerance
- you currently have a peptic (stomach) ulcer

- you have or have had inflammation of the lining of the stomach or intestines (e.g. Crohn's Disease or Ulcerative Colitis)
- you have severe liver or kidney problems
- you are currently taking other medicines known as: sulfinpyrazone (used to treat gout), fluconazole (used to treat fungal infections) or certain sulfur antibiotics (eg. sulfaphenazole or 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 Moxicam passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to children and adolescents under 18 years of age.

Safety and effectiveness in children younger than 18 years 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 Moxicam, 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 problems
- asthma or any other breathing problems.

Tell your doctor if you are pregnant, planning to become pregnant.

Like most NSAID medicines, meloxicam is not recommended for use during pregnancy. If there is a need to consider meloxicam during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

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

NSAID medicines, like meloxicam may decrease the effectiveness of IUDs.

Tell your doctor if you currently have an infection.

Moxicam 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 Moxicam.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and Moxicam may interfere with each other. These include:

- aspirin, salicylates or other NSAID medicines
- 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
- ciclosporin, 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 (drugs usually used to treat inflammatory conditions, such as skin rash and asthma)
- some medicines used to treat infections (e.g. erythromycin, sulfur antibiotics, ketoconazole, itraconazole)
- some medicines used to treat irregular heart beats (e.g. amiodarone and quinidine)
- pemetrexed, a medicine used in the treatment of certain lung cancers.

These medicines may be affected by Moxicam 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 may have more information on medicines to be careful with or avoid while taking this medicine.

How to take Moxicam

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 container label, ask your doctor or pharmacist.

How much to take

For the treatment of osteoarthritis

The usual dose of Moxicam 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 15mg taken as a single dose each day.

For the treatment of rheumatoid arthritis

The usual dose of Moxicam 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 Moxicam 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 with a full glass of water.

When to take it

Take your medicine at about the same time each day, either morning or evening.

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

Take Moxicam during or immediately after food.

This will reduce the chance of a stomach upset.

How long to take it for

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

This medicine will not cure your condition but it does not cure it. It is important to keep taking your medicine even if you feel well.

You may need to take Moxicam for a long time. Keep in touch with your doctor during this time.

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 the 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 Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Moxicam. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose with Moxicam may include:

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

While you are taking Moxicam

Things you must do

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

Moxicam can slow down blood clotting.

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

If you get an infection while using Moxicam, tell your doctor.

Moxicam may hide some of the signs of an infection (e.g. pain, fever, redness and swelling). You may think, mistakenly, that you are better or that the infection is not serious.

Things you must not do

Do not use Moxicam 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 Moxicam affects you.

As with other NSAID medicines, Moxicam 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 Moxicam.

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 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, vomiting, heartburn, indigestion, belching, cramps or pain
- constipation, diarrhoea or wind
- headache
- 'flu'-like symptoms, including runny or blocked nose, coughing, sore mouth or throat, discomfort when swallowing

- 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, buzzing, ringing or other persistent noise in the ears.

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
- severe pain or tenderness in the stomach
- severe dizziness
- collapse or fainting, shortness of breath or tiredness, chest pain, swollen or sore leg veins
- yellowing of the skin and eyes, known as jaundice
- flaking of the skin

- 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).

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, stop taking Moxicam and either tell your doctor immediately or go to Accident and 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 or visual disturbances

The above list includes 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 that is making you feel unwell.

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

After taking Moxicam

Storage

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

If you take the tablets out of the pack they will not keep well.

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

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

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking Moxicam, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Moxicam tablets are available in two strengths: -

- Moxicam 7.5mg - Light green / light green, size '2' hard gelatin capsules filled with light yellow coloured granules.
- Moxicam 15mg - Light green/light yellow, size '2' hard gelatin capsules filled with light yellow coloured granules.

Ingredients

The active ingredient in Moxicam is meloxicam.

Each Moxicam 7.5 tablet contains 7.5 mg of meloxicam.

Each Moxicam 15 tablet contains 15 mg of meloxicam.

The tablets also contain the following inactive ingredients:

- lactose monohydrate
- maize starch
- sodium citrate
- magnesium stearate
- Brilliant Blue FCF
- Sunset Yellow FCF

- gelatin
- titanium dioxide
- quinolone yellow (15 mg strength only)

Supplier

Moxicam is supplied by:

Alphapharm Pty Limited

Level 1, 30 The Bond

30 - 34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

Moxicam 7.5 - AUST R 232584

Moxicam 15 - AUST R 232585

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