

Consumer Medicine Information**What is in this leaflet**

This leaflet answers some common questions about MOVALIS.

It does not contain all of 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 MOVALIS against the benefits they expect it will have 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 MOVALIS is used for

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

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

MOVALIS belongs to a family of medicines called Non-Steroidal Anti-inflammatory Drugs (NSAIDs). These medicines work by relieving pain and inflammation.

It is available only with a doctor's prescription.

Your doctor may have prescribed MOVALIS for another reason. Ask your doctor if you have any questions about why MOVALIS has been prescribed for you.

Before you take it*When you must not take it*

Do not take MOVALIS if you are allergic to:

- meloxicam
- aspirin or other NSAIDs
- any of the ingredients listed at the end of this leaflet (this includes lactose).

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

Do not take MOVALIS 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 you have a bleeding disorder
- you have a galactose intolerance
- you have a peptic (stomach) ulcer
- 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 kidney problems
- you have severe liver 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 MOVALIS if you are breastfeeding.

MOVALIS may pass into breast milk and may affect your baby.

Do not take MOVALIS if the expiry date (Exp.) printed on the pack has passed.

Do not take MOVALIS if the packaging shows signs of tampering or the capsules do not look quite right.

Do not give MOVALIS to children or adolescents under 18 years of age.

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

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 including aspirin and other NSAIDs
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have, any medical conditions, especially the following:

- 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 if you are pregnant or intend to become pregnant.

Like most NSAID medicines, MOVALIS is not recommended for use during pregnancy. If there is a need to consider MOVALIS 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 for birth control.

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

Tell your doctor if you currently have an infection.

MOVALIS 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.

Tell your doctor if you are taking any medicines used to treat high blood pressure and some other heart problems such as ACE inhibitors, angiotensin receptor antagonists and diuretics (also called fluid or water tablets).

Taking it together with these medicines can cause kidney problems.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a

pharmacy, supermarket or health food shop.

Some medicines may be affected by MOVALIS, or may affect how well it works. These include:

- aspirin, salicylates or other NSAID medicines
- medicines used to thin your blood (such as warfarin, heparin and ticlopidine)
- 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 (a painful joint disease) and some types of cancer
- ciclosporin, a medicine used to treat rheumatoid arthritis and certain problems with the immune system
- diuretics, also called fluid or water tablets
- medicines used to treat high blood pressure
- medicines used to treat heart problems
- 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 fungal infections
- some sulfur antibiotics
- some medicines used to treat irregular heartbeats
- terfenadine and astemizole, medicines used to prevent or relieve the symptoms of allergy, such as hay fever or insect stings
- pemetrexed, a medicine used in the treatment of certain lung cancer

Your doctor can tell you what to do if you are taking any of these medicines.

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

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 MOVALIS.

How to take it

Follow all directions given to you by your doctor and 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 MOVALIS is 7.5 mg, taken as a single dose each day.

However, your doctor will prescribe a dose suitable for your condition.

For the treatment of rheumatoid arthritis

The usual dose of MOVALIS 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 MOVALIS 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 capsules with a glass of fluid.

It is best to take it immediately after food to avoid the chance of an upset stomach.

Try to take MOVALIS at 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.

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 the missed dose as soon as you remember, and then go back to taking your capsules as you would normally.

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

How long to take it for

Keep taking MOVALIS every day for as long as your doctor recommends.

It will not cure your condition, but it should help control pain, stiffness and swelling. It is important to keep taking your medicine even if you feel well.

If you take too much (overdose)

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

You may need urgent medical attention.

Signs of an overdose 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 it

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking MOVALIS.

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

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

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

MOVALIS can slow down blood clotting.

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

MOVALIS may hide some of the signs of an infection (eg. 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 MOVALIS to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

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

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

Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you are not alert.

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 MOVALIS.

Like all other medicines, it may have unwanted side effects in some people. 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 notice any of the following and they worry you:

- stomach upset including nausea, vomiting, heartburn, indigestion, belching, cramps or pain
- headache
- sore throat or discomfort when swallowing
- 'flu'-like symptoms, including coughing
- constipation, diarrhoea or wind
- dizziness or light-headedness, falls or other accidents around the home or work
- skin rash or itching
- back pain, muscle spasms or pain, painful or swollen joints
- clicking sounds when joints move
- trouble sleeping
- laryngitis, a condition causing hoarseness or loss of voice
- skin rashes, which may be caused by exposure to sunlight, that can blister and may take on the appearance of a severe burn
- increase in blood pressure
- tinnitus (ringing in the ear).

These side effects are usually mild.

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

- infections in your lungs, throat or nose
- sinusitis, a condition causing a feeling of tension or fullness of the nose, cheeks and behind your eyes
- blurred vision
- infections in your urinary tract, eg. the need to pass urine more frequently than normal, any change in the amount or colour of your urine (red or brown) or painful urination
- collapse or fainting, shortness of breath or tiredness, fast or irregular heartbeat (also called palpitations), chest pain, swollen or sore leg veins
- severe pain or tenderness in the stomach
- severe dizziness
- 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 (eg. lips, mouth, eyes or genitals)

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

If any of the following happen, stop taking it and tell your doctor immediately, or go to Accident and Emergency at the 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.

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

Not all of these side effects have been reported with MOVALIS but have been seen with similar medicines.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using it

Storage

Keep MOVALIS 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.

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

If you take them out of their packaging they may not keep well.

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

Do not store MOVALIS or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

MOVALIS capsules come in 2 strengths:

- MOVALIS 7.5 mg - pale green capsules, printed with 59D in black.
- MOVALIS 15 mg - pale yellow/pale green capsule, printed with 77C in black.

Each pack contains 30 capsules.

Ingredients

The active ingredient in MOVALIS is meloxicam:

- each MOVALIS 7.5 mg capsule contains 7.5 mg of meloxicam
- each MOVALIS 15 mg capsule contains 15 mg of meloxicam.

The capsules also contain:

- sodium citrate dihydrate
- lactose monohydrate
- maize starch
- magnesium stearate
- gelatine
- indigo carmine CI73015
- iron oxide yellow CI77492
- titanium dioxide
- black printing ink.

The capsules are gluten free.

Supplier

MOVALIS is supplied by:

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

Australian registration numbers:

MOVALIS 7.5 mg capsule
- AUST R 142228

MOVALIS 15 mg capsule
- AUST R 142229

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