

AROXICAM

Meloxicam Tablets 7.5mg and 15mg

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What AROXICAM is used for

AROXICAM is used for the relief of pain and inflammation of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

How AROXICAM works

AROXICAM belongs to a class of medication known as Non-Steroidal Anti-Inflammatory Drugs (NSAID's). They help to relieve pain, inflammation and fever by inhibiting the production of the substance that cause it.

Before you use AROXICAM

- When you must not use it

Do not take this medicine if:

- you are allergic to meloxicam, aspirin or any other types of NSAID's or any other ingredients of this medicine (listed in Product Description)
- if you have had asthma, angioedema (swelling of your skin), urticarial (itching or hives), nasal polyps and the symptoms become worsen caused by Aspirin or NSAIDs.
- Active gastric intestinal ulcer or history of recurrent gastro intestinal ulcer.
- If you have severe kidney and liver problems
- Children under 12 years old, except if approved for the use in Juvenile Rheumatoid Arthritis
- You experience bleeding from the stomach, gut or any other bleeding.
- Pregnant or breast feeding Ask your doctor or pharmacist for advice before taking any medicine. If you are not sure whether you should start using this medicine, talk to your doctor or pharmacist.

- Before you start to use it

Tell your doctor or pharmacist if you have an allergy to AROXICAM, aspirin or any other NSAIDs.

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

- High blood pressure or fluid retention
- Asthma or any other breathing problems.

- if you have ulceration, bleeding or perforation of your stomach or intestines
- Kidney, liver or heart disease
- Elderly
- Dehydrated
- Patients with rare hereditary problems of galactose intolerance, the Lapp-lactase deficiency or glucose galactose malabsorption.

Tell your doctor if you are pregnant, planning to become pregnant, breast feeding or plan to breast-feed.

- Taking other medicines

Tell your doctor or pharmacist 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 interfere with AROXICAM Tablets. These include:

- Aspirin or other NSAIDs
- Medicines used for blood thinning like ticlopidine, clopidogrel
- Medicines used to treat high blood pressure and other heart problems
- Lithium, a type of medicine used to treat depression
- Methotrexate, a type of medicine used to treat rheumatoid arthritis and some types of cancer
- Cyclosporin, a type of medicine known as immunosuppressant. It is used by those who have undergone an organ transplant to prevent rejection.
- Cholestyramine, a type of medicine used to treat high cholesterol levels.
- Intrauterine devices.

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

How to use AROXICAM

Always take the medicine exactly as your doctor or pharmacist has told you. Read the direction labels carefully. If you have any concerns about how to take this medicine, talk to your doctor or pharmacist.

- How much to use

Osteoarthritis (degenerative joint disease):

7.5 mg/ day. If necessary, the dose may be increased to 15mg/ day.

Rheumatoid arthritis (chronic joint inflammation):

15mg/ day. According to the therapeutic response, the dose may be reduced to 7.5mg/ day.

Ankylosing spondylitis (a type of arthritis that affects the spine):

In patients with increased risk of adverse events, start treatment with 7.5mg/ day.

Severe kidney failure:

In dialysis patients with severe renal failure, the dose should not exceed 7.5mg/ day. The total daily dosage should not exceed 15mg.

Elderly:

In elderly patients treated for rheumatoid arthritis the recommended dose for long term treatment is 7.5mg/day.

Children (under 15 years old):

Not recommended

- When to use it

Use as directed by your doctor or pharmacist.

The tablet should be swallowed with water, or another drink, with food.

- How long to use it Use

AROXICAM for the duration that the doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using AROXICAM.

Tell your doctor immediately if you become pregnant while using this medication.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give AROXICAM to anyone else, even if they have the same symptoms or condition as you.

AROXICAM

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- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

If you are pregnant, trying to get pregnant or are breast-feeding, you should not take AROXICAM without discussing it with your doctor first

Side effects

Like all medicines, AROXICAM can cause side effects, although not everybody gets them.

Hematological (Blood): anemia (condition caused by low red blood cell), disturbances of blood count, including abnormal reduction in white cell count, leucocytopenia (reduction of white blood cell) and thrombocytopenia (deficiency platelets in blood).

Hypersensitivity Reactions: angio oedema and immediate hypersensitivity reactions including anaphylactoid / anaphylactic reactions.

Central Nervous System: lightheadedness and headache, vertigo (spinning sensation), tinnitus (ringing in the ear), drowsiness and confusion.

Respiratory: asthma

Stomach and intestine: Dyspepsia (indigestion), nausea, vomiting, abdominal pain, constipation, flatulence (excessive air in the body) and diarrhea, esophagitis (inflammation of the esophagus), gastro-duodenal ulcer, stomach and intestinal bleeding, stomach and intestinal perforation, colitis (inflammation of the lining of the colon), hepatitis (inflammation of the liver), gastritis (inflammation of the lining of the stomach).

Dermatological (Skin): pruritus (itching) and skin rash, and urticaria (hives), Stevens-Johnson syndrome and toxic epidermal necrolysis, angioedema, bullous reactions such as erythema multiforme, photosensitivity reaction.

Kidney: Abnormal renal function parameters (increased serum creatinine and/or serum urea), acute kidney failure.

Eye Disorders: visual disturbances including blurred vision

Cardiac and Vascular Disorders: Palpitations, increase in blood pressure, flushes.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of AROXICAM

- Storage

Keep out of the reach and sight of children. Store in a dry place below 30 °C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

AROXICAM TABLETS 7.5MG:

Light yellow, round, uncoated, tablet with score line between 'F' and '1' debossed on one side and plain on the other side.

AROXICAM TABLETS 15MG:

Light yellow, round, uncoated, tablet with score line between 'F' and '2' debossed on one side and plain on the other side.

- Ingredients

- Active ingredient:

Meloxicam

- Inactive ingredients

Magnesium stearate, povidone, cellulose microcrystalline, sodium citrate, crospovidone, lactose monohydrate, silica colloidal anhydrous, purified water

- MAL number(s):

AROXICAM Tablets 7.5mg:

MAL08111909AZ

AROXICAM Tablets 15mg:

MAL08111899AZ

Manufacturer

AUROBINDO PHARMA LTD.

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Product Registration Holder

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