

Melorex

Meloxicam 7.5mg and 15 mg Tablets

What is in this leaflet

This leaflet answers some common questions about MELOREX.

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 MELOREX 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 MELOREX is used for

MELOREX is used to treat the symptoms of:

- osteoarthritis
- rheumatoid arthritis

Both diseases mainly affect the joints causing pain and swelling. MELOREX can relieve symptoms such as pain and inflammation (swelling, redness and soreness), however, it will not cure your condition.

MELOREX belongs to a family of medicines called Non-Steroidal Antiinflammatory Drugs (NSAIDs). These medicines work by relieving pain and inflammation. Ask your doctor if you have any questions about why MELOREX has been prescribed for you. Your doctor may have prescribed MELOREX for another reason.

Before you take MELOREX

When you must not take MELOREX

Do not take MELOREX if you have an allergy to:

- the active ingredient, meloxicam, or any of the other ingredients in MELOREX listed at the end of this leaflet (see ingredients). 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.

Ask your doctor if you are unsure if you are allergic to these ingredients.

Do not take MELOREX 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 or you have previously had a heart attack
- 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
- you are pregnant or intend to become pregnant
- you are breastfeeding, or intend to breastfeed. The active ingredient in MELOREX may pass into breast milk and may affect your baby.
- you currently or within the last 6 months have had a peptic (stomach) ulcer
- you have Crohn's Disease or Ulcerative Colitis
- you have severe liver or kidney problems
- you are undergoing major surgery and have a high risk of heart disease (including diabetes, high cholesterol and smokers).

Do not give MELOREX to children and adolescents under 12 years of age.

Do not take MELOREX if the packaging is torn or shows signs of tampering. Do not take MELOREX if the EXPIRY DATE printed on the pack has passed.

Before you start to take MELOREX

You must tell your doctor or pharmacist if:

1. you have any allergies to any other medicines, including aspirin or other NSAID medicines
2. you have or have had 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.
3. you are using an IUD for birth control
4. you are taking MELOREX together with 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). When taken together these medicines can cause kidney problems. If you have not told your doctor or pharmacist about any of the above, tell them before you start taking MELOREX.

Taking other medicines

Before taking MELOREX, tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop. There may be interference between MELOREX and some medicines. 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
- cyclosporin, 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
- cholestyramine, a medicine used to treat high cholesterol levels in the blood
- corticosteroids (medicines 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 heart beats
- some antihistamines (medicines used to prevent or relieve the symptoms of allergy, such as hay fever or insect stings).

These medicines may be affected by MELOREX or may affect how well MELOREX works. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking MELOREX.

How to take MELOREX

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 MELOREX 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 MELOREX 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 MELOREX 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 MELOREX

Swallow the tablets with fluid. It is best to take MELOREX immediately after food to avoid the chance of an upset stomach. Try to take MELOREX at the same time each day, either morning or evening.

How long to take MELOREX

Keep taking MELOREX every day until your doctor tells you to stop. MELOREX will not cure your condition but it should help control pain, swelling and stiffness.

If you forget to take MELOREX

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 try to make up for missed doses by taking more than one dose at a time. If you are not sure what to do, check with your doctor or pharmacist.

If you have taken too much MELOREX (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice if you think that you or anyone else may have taken too much MELOREX. Do this even if there are no signs of discomfort or poisoning.

While you are taking MELOREX

Things you must do

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

If you are about to start any new medicines, tell your doctor and pharmacist that you are taking MELOREX.

If you are going to have surgery, including dental surgery, tell your doctor or dentist that you are taking MELOREX. MELOREX can slow down blood clotting.

If you get an infection while using MELOREX, tell your doctor. MELOREX 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 to be careful of

Be careful driving or operating machinery until you know how MELOREX affects you. As with other NSAID medicines, MELOREX may cause dizziness, drowsiness or blurred vision in some people. Make sure you know how you react to MELOREX before you drive a car, operate machinery, or do anything else that could be dangerous if you are not alert.

Side effects

You should be aware that all medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing. Check with your doctor as soon as possible if you have any problems while taking MELOREX, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

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 mouth or throat, discomfort when swallowing
- constipation, diarrhoea or wind
- dizziness or light-headedness
- skin rash or itching
- skin rashes, which may be caused by exposure to sunlight, 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:

- blurred vision
- any change in the amount or colour of your urine (red or brown)
- any pain or difficulty experienced when urinating
- 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 (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, STOP taking MELOREX and 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.

Not all of these side effects have been reported with MELOREX but have been seen with similar medicines. Other side effects not listed above may occur in some people.

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using MELOREX

Storage

Keep MELOREX 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 tablets in the container until it is time to take them.

If you take the tablets out of the container, they may not keep well.

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

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

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

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking MELOREX, ask your pharmacist what to do with any that are left over.

Product Description***What MELOREX looks like***

MELOREX 7.5 mg are pale yellow coloured, circular flat beveled uncoated tablets.
MELOREX 15 mg tablets are pale yellow coloured, circular flat beveled uncoated tablets with a central breakline on one side and plain on the other.

Ingredients

The active ingredient in MELOREX is meloxicam. Each MELOREX 7.5 mg tablet contains 7.5 mg of meloxicam. Each MELOREX 15 mg tablet contains 15 mg of meloxicam.

The tablets also contain: Colloidal anhydrous silica, Pregelatinised starch, Lactose monohydrate, Magnesium stearate, Maize starch, Microcrystalline cellulose, Sodium citrate dihydrate

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Distributor

Douglas Pharmaceuticals Ltd, P.O. Box 45027, Auckland 0651
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