

New Zealand Consumer Medicine Information

Melorex

Meloxicam 7.5 mg and 15 mg Tablets

What is in this leaflet

The information enclosed answers several general questions about Melorex.

This leaflet does not include all available information on Melorex.

All medication has benefits and risks. Your doctor will have considered the risks of you using Melorex against the benefits expected.

Discuss with your doctor any concerns you may have.

This leaflet was last updated on the date at the end of this leaflet.

Check with your doctor or pharmacist to make sure you have the most up to date information on Melorex as there may be new information available.

The most recent leaflet available for Melorex can be found at www.medsafe.govt.nz

Keep this information with your medicine and refer to this leaflet if you have any queries.

What Melorex is used for

Melorex is used for the treatment of symptoms of:

- Osteoarthritis.
- Rheumatoid arthritis.

Osteoarthritis and rheumatoid arthritis primarily cause swelling and pain in the joints. Melorex helps to alleviate the pain and inflammation but will not cure the disease.

Melorex contains the active ingredient meloxicam, which belongs to the group of medicines known as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). NSAIDs work by alleviating inflammation and pain.

If you have any concerns about why Melorex has been prescribed, please discuss this with your doctor.

Your doctor may have prescribed Melorex for a different reason.

Melorex is only accessible with a prescription from your doctor.

Before you use Melorex

Do not use Melorex if you are allergic to:

- meloxicam, or any of the other ingredients in Melorex (listed on the back of this leaflet). This includes rare inherited conditions of galactose intolerance.
- any NSAID medications.
- aspirin.

Seek immediate medical attention if you experience any of the following side effects, as you may be allergic to this medicine:

- Itching, rash, or reddened skin.
- Swelling of the eye lids, lips, face, and throat.
- Increase in wheezing and shortness of breath.
- Feeling faint or dizzy.

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

If you have any concerns on whether Melorex is right for you, discuss with your doctor.

Do not use Melorex if you:

- are about to have surgery of the heart (including a coronary artery bypass graft or major vascular surgery).
- have had bleeding from the gut or stomach or any other type of bleeding.
- have had a heart attack.
- have a heart disease which includes shortness of breath, have swelling of the lips or feet because of fluid build-up.
- have had a stroke which resulted from a brain bleed or you have a bleeding disorder.
- are pregnant or are planning to be pregnant.
- are breastfeeding or anticipate breastfeeding. It is known that the active ingredient in Melorex may transfer into the breast milk and have an effect on your baby.
- currently or within the last 6 months, have had a peptic (stomach) ulcer.
- have or have previously had inflammation of the bowel or stomach lining (Ulcerative Colitis on the lining of the stomach or bowel inflammation or Crohn's Disease).
- have severe kidney (without dialysis) or severe liver problems.
- you are galactose intolerant.

Do not give Melorex to children and adolescents under 12 years of age as the safety and efficacy for this age group has not been established.

Do not use after the expiry date. The expiry date can be found on the blister and on the carton.

If the packaging of the Melorex carton or blister displays signs of damage or tampering do not use.

If you have any concerns about using Melorex, ask your doctor or pharmacist.

Please inform your doctor **before** using Melorex if you are currently being treated or have in

the past been treated for any other medical conditions. It is important that you discuss the below conditions with your doctor as some of these problems may become worse during Melorex treatment. Your doctor may change your treatment due to the below conditions if required:

- Asthma or any other respiratory conditions.
- Diabetes.
- Fluid retention.
- High blood pressure.
- High cholesterol.
- Kidney disease.
- Liver disease.
- Stomach concerns (for example, indigestion, heartburn, or stomach ulcers).

Inform your doctor if you:

- Use an IUD for contraception. NSAID medications may reduce IUD effectiveness.
- Have an infection at present. Melorex may conceal some infection symptoms (for example; fever, pain, redness and/or swelling). As a result, you may believe that the infection is mild when it could be serious.
- Have an allergy to any dyes, preservatives, foods, or other medications.

Using other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including any medicines obtained without a prescription from your pharmacy, health store or supermarket.

Tell your doctor if you are taking any of the following medications as they may cause kidney problems when taken in combination with Melorex:

- Aspirin, any other NSAID medications or salicylates.
- Medication to treat high blood pressure and/or problems of the heart (for example; angiotensin receptor antagonists, ACE inhibitors and/or diuretics (water or fluid tablets)).
- Medication to help thin your blood (for example; heparin, ticlopidine or warfarin).

If you use Melorex with some other medications, the effect of Melorex or the other medicine may be altered.

Tell your doctor if you are taking the following:

- Antidepressants (Selective Serotonin Reuptake Inhibitors or SSRIs).
- Antihistamine medication used for the prevention or to alleviate allergy symptoms such as insect bites and hayfever (for example; astemizole and terfenadine).
- Cholestyramine which is used for the treatment of high cholesterol blood levels.
- Corticosteroids which are used for the treatment of inflammatory conditions (for example; asthma and skin rashes).
- Cyclosporin which is used for the treatment of rheumatoid arthritis and immune system problems.

- Lithium which is used for the treatment of depression.
- Medication used for the treatment of diabetes (for example; nateglinide and sulfonylureas).
- Medication used for the treatment of infections (for example; erythromycin, itraconazole, ketoconazole and sulfur antibiotics).
- Medication used for the treatment of irregular heartbeats (for example; quinidine and amiodarone).
- Medication used for the treatment of some lung cancers (for example; pemetrexed).
- Methotrexate which is used for the treatment of rheumatoid arthritis and several forms of cancer.

Your doctor will discuss with you what to do if you are taking any of the above medications.

Your doctor may instruct you to take a modified amount of the above medications or you may be instructed to change your medication completely.

How to use Melorex

It is important that you follow the prescribed instructions your doctor gave you on the dosage of Melorex and the duration you should take it.

How much Melorex to take and how to take it

Your doctor will prescribe you the lowest dose of Melorex for your condition. This is to help reduce any unwanted side effects that may occur.

Osteoarthritis Treatment

The usual dose of Melorex is 7.5 mg, taken as an individual dose once per day. Your doctor will prescribe a dose suitable for your condition.

The dose may be increased to the maximum recommended dose of 15 mg per day if your doctor feels it is necessary.

Rheumatoid Arthritis Treatment

The usual dose of Melorex is 15 mg taken as an individual dose once per day. Depending on your response, the dose may be reduced to 7.5 mg once per day if your doctor feels this is required. 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.

Your Melorex dose may be restricted to 7.5 mg once per day if any of the medical conditions apply to you that are recorded under the **Before you use Melorex** section.

Melorex is not recommended for use in individuals aged younger than 12 years.

Swallow the Melorex tablet with a large glass of water.

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

Try to take Melorex at about the same time to avoid missing any of your doses.

How long to take Melorex

Melorex is a long-term treatment. It is essential that you continue to take Melorex even when you feel in good health. Melorex helps to control the pain and inflammation but does not cure the condition.

Make sure you continue to take Melorex for as long as your doctor thinks is necessary.

If you forget to take Melorex

If you have forgotten to take your normal dose at the correct time, take your next dose as soon as you remember. However, if you forget to take Melorex close to the time of the next dose (for example; within two to three hours) then simply miss out the dose you have forgotten.

Do not take a double dose of Melorex at any given time if you have missed a dose.

If you have difficulty remembering when your next dose of Melorex is due, talk to your pharmacist for advice.

In case of overdose

If you have received more Melorex than you should (overdose)

If you or someone else takes too much Melorex, immediately phone the Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or your doctor or go to your nearest Accident and Emergency Department even if you do not feel unwell or there are no signs of overdose symptoms.

Keep these telephone numbers and information in an easily accessible place.

Overdose signs and symptoms may involve:

- Breathing difficulties.
- Drowsiness.
- Feeling dizzy.
- Headache.
- Impaired consciousness.
- Kidney failure.
- Low blood pressure.
- Nausea.
- Seizures or fits.
- Vision that is blurred.
- Vomiting.

While you are using Melorex

Important advice

Abide by all instructions given by your doctor carefully as they may be different from the information provided in this leaflet.

Tell your doctor without delay if you become pregnant while you are taking Melorex.

If you are considering taking any other medicine while you are using Melorex, tell your doctor, pharmacist, and dentist.

Make sure that all doctors, pharmacists and dentists who are working with you know that you are taking Melorex, especially if you are due to undergo surgery, as Melorex can reduce the speed of blood clotting.

If you experience an infection while taking Melorex, inform your doctor. Melorex may conceal some infection symptoms (for example; fever, pain redness and/or swelling). As a result, you may believe that the infection is mild when it may be serious.

Melorex should not be used to treat any other health condition, except if your doctor advises you to.

This medicine has been prescribed for you personally. Do not give it to anyone else even if their symptoms are the same as yours, as it may harm them.

Do not suddenly stop taking Melorex or change your dose of Melorex before you have spoken with your doctor.

Driving and using machinery

Take care when driving or using machines until you are aware of how Melorex may affect you.

As with other NSAID medicines, Melorex may cause you to experienced blurred vision, dizziness or drowsiness. 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

Discuss with your doctor or pharmacist any questions or concerns you may have.

All medications can have side effects. For most people who experience side effects, they are usually mild and pass over a short time. At times they can be serious and some side effects may require you to have medical treatment.

Discuss with your doctor if you experience any changes to your condition as it can sometimes be difficult to determine whether changes are a result of your condition or a side effect from taking Melorex or another medication.

Do not be concerned by the side effects below, however if you experience any of these

side effects and they are causing concern, please talk to your doctor or pharmacist.

Common side effects:

- Blood pressure increase.
- Constipation.
- Diarrhoea.
- Feeling dizzy or light-headed.
- Flatulence.
- Flu-like symptoms (for example; cough, hard to swallow, runny or congested nose, sore throat, or mouth).
- Headache.
- Skin rashes (may look like a severe burn with blisters and itchy and caused by sunlight exposure).
- Stomach concerns (for example; belching, cramps, heartburn, indigestion, nausea, pain, or vomiting).
- Tinnitus (experiencing ringing in the ears).

The side effects below can be serious. If you experience any of the below, immediately tell your doctor or seek medical attention.

- Blurred vision.
- Changes in the colour of urine (brown or red) or the amount of your urine.
- Chest pain.
- Dizziness that is severe.
- Feeling faint or collapsing.
- Indications of anaemia (for example; paleness, shortness of breath and feeling tired).
- Irregular or fast heartbeat (palpitations).
- Jaundice (yellow eyes and skin).
- Mucous membranes that are irritated (for example; eyes, genitals, lips, and mouth).
- Pain or difficulty when urinating.
- Pain that is severe or tenderness in the stomach.
- Painful or swollen leg veins.
- Shortness of breath or feeling tired.
- Skin that is flaking.
- Swelling of your body (legs, ankles, or other parts).

Go immediately to your nearest hospital or Accident and Emergency Department and STOP taking Melorex if you experience the following side effects:

- Allergy symptoms, for example; severe itching and/or skin rash.
- Asthma, shortness of breath or wheezing.
- Blurred vision (disturbances to your vision), speech that is slurred and a weakness on one side of your body.
- Bleeding from your rectum, bloody diarrhoea or black sticky stools.
- Face, lips, tongue, throat swelling which may cause breathing or swallowing to become difficult.
- Vomiting of matter that looks like coffee grounds or blood.

These side effects are rare but very serious. You may require urgent medical attention or to be admitted to hospital.

Not all of the above side effects have been observed with Melorex but have been reported with comparable medicines.

If you experience any other side effects that are not discussed above, tell your doctor without delay.

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

After using Melorex

Storage of Melorex

Keep out of reach of children by storing Melorex in a locked cabinet at a height that is hard to reach for children.

Avoid direct sunlight or heat. Do not store Melorex in your car on a hot day or on a windowsill.

Store Melorex below 25°C. Protect from light and moisture.

Keep Melorex tablets in their pack until you are about to take them.

The expiry date is the last day of the expiry month.

Disposal

If your doctor advises you to stop taking Melorex, or they have exceeded their expiry date, request information from your pharmacist on what to do with any product that is left over.

Product Description

What Melorex looks like

Melorex 7.5 mg tablets are pale yellow, circular, flat, beveled, uncoated tablets, plain on both sides.

Melorex 15 mg tablets are pale yellow, 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.

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