Package leaflet: Information for the patient

Areloger 7.5 mg Tablets
Areloger 15 mg Tablets
meloxicam

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Areloger is and what it is used for

Areloger contains the active ingredient meloxicam. Meloxicam belongs to the group of non-steroidal anti-inflammatory drugs (NSAIDs) used for the treatment of pain and inflammation in muscles and joints.

Areloger can be used by adults and adolescents over 16 years of age for:
- the short-term treatment of flare-ups of osteoarthrosis (a disease of the joints)
- the long-term treatment of pain in connection with rheumatoid arthritis (inflammation of the joints)
- the long-term treatment of a similar condition called ankylosing spondylitis (inflammation of the spine).

2. What you need to know before you take Areloger

Do not take Areloger
- during the last three months of pregnancy
- if you are a child or adolescent under 16 years of age
- if you are allergic to meloxicam or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to acetylsalicylic acid (e.g. aspirin) or other non-steroidal anti-inflammatory drugs (NSAIDs)

- if you have previously had symptoms of wheezing, chest tightness, breathlessness (asthma), swellings inside the nose causing blockages (nasal polyps), swelling around the eyes, face, lips, mouth or throat, leading to difficulty breathing (angioneurotic oedema) or a nettle rash known as hives (urticaria) following treatment with acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs)
- if you currently have a bleed in the stomach or bowel
- if you have or have had two or more episodes of ulcers or bleeding in the stomach or bowel
- if you have ever had bleeding or tears (perforations) in the stomach or bowel after using an NSAID
- if you have, or have had a bleeding disorder or bleeding in the brain (cerebrovascular bleeding)
- if you have severe liver problems
- if you have severe kidney failure and are not receiving dialysis
- if you suffer from severe heart failure.

Warnings and precautions
Talk to your doctor or pharmacist before taking Areloger

- if you have ever developed fixed drug eruption (round or oval patches of redness and swelling of the skin that usually recurs at the same site(s), blistering, hives and itching) after taking meloxicam or other oxicams (e.g. piroxicam)
- if you have previously had inflammation of the food pipe (oesophagitis); inflammation of the stomach lining (gastritis) and/or a stomach ulcer as your doctor will need to check you no longer have these before you start treatment
- if you have a history of problems with your stomach or gut (such as Crohn's disease or ulcerative colitis)
- if you are elderly (because of increased side effects)
- if you have a very low blood volume (you may have had a large loss of blood, surgery or low fluid intake)
- if you have other liver, kidney or heart problems
- if you have high levels of potassium in your blood
- if you are trying to become pregnant or undergoing investigations of fertility

Medicines such as Areloger may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. **Do not** exceed the recommended dose or duration of treatment.

If you have heart problems (including angina or reduced circulation), previous stroke or think that you might be at risk of these conditions (for example if you have a high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Areloger, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).

These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Areloger, you must not be re-started on meloxicam at any time. If you develop a rash or these skin

symptoms, stop taking Areloger, seek urgent advice from a doctor and tell them that you are taking this medicine.

During treatment
Speak to your doctor immediately if you get stomach or bowel problems (particularly bleeding) in the first few days after you start taking Areloger. This may be more likely to occur if you have had problems with your gut in the past, or if you are elderly. Bleeding in the gut may be noticed as black tar-like stools or if you are sick, it may contain red or dark blood particles that look like coffee grounds (see section 4).

This medicine may affect the results of certain blood or urine tests. Always tell your doctor or hospital staff that you are taking this medicine if you need to have tests.
This medicine may mask the symptoms of certain infections. For example, it may mask fever. If you feel unwell and think you may have an infection talk to your doctor.

Other medicines and Areloger

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription. The following medicines can affect or be affected by Areloger:

- anticoagulants (medicines used to stop your blood clotting) such as warfarin, heparin, clopidogrel, dabigatran, apixaban and ticlopidine as meloxicam can increase their effect or you may be more likely to bleed
- other non-steroidal anti-inflammatory drugs (NSAIDs) such as acetylsalicylic acid (aspirin) or medicines known as 'COX-2 inhibitors' such as celecoxib
- lithium (a medicine used for mental health conditions)
- methotrexate (a medicine used for psoriasis, inflammation and some cancers)
- thrombolytics (medicines used for heart conditions to dissolve blood clots)
- cholestyramine (a medicine used for reducing levels of cholesterol in the blood)
- calcineurin inhibitors (medicines used to treat autoimmune diseases such as rheumatoid arthritis or used after organ transplant) such as ciclosporin or tacrolimus
- diuretics (water tablets)
- medicines to treat high blood pressure called ACE inhibitors, angiotensin II antagonists (sartans) or beta blockers
- corticosteroids (for asthma, inflammation and after organ transplant surgery) as you may be more likely to have ulcers or bleeding
- selective serotonin-reuptake inhibitors, (SSRIs) (medicines used for depression)
- pemetrexed, a medicine used to treat certain cancers. You may need to stop taking this medicine for at least 5 days before, during and 2 days after receiving pemetrexed
- medicines which can increase levels of potassium in the blood. This includes potassium salts or supplements, certain water tablets (diuretics e.g. spironolactone) or the antibiotic trimethoprim
- deferasirox, a medicine used to reduce levels of iron in the body
- oral anti-diabetics (sulfonylureas, nateglinide) - medicines used to treat diabetes. Your doctor should carefully monitor your blood sugar for the risk of hypoglycemia

Pregnancy, breast-feeding and fertility

Pregnancy
Do not take this medicine during the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Areloger during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor.

If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Areloger can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breast-feeding
NSAIDs can pass into breast milk. You should not breast-feed whilst taking this medicine.

Fertility
This medicine may make it more difficult to become pregnant. Tell your doctor if you are planning to have a baby or if you are undergoing investigation of fertility.

Driving and using machines

Areloger may cause side effects that can affect a person's ability to drive and use machinery. Examples of side effects include visual disturbances such as blurred vision, drowsiness, dizziness, a spinning sensation (vertigo) or other problems affecting the brain. If you suffer from any of these side effects it is advisable to refrain from driving or using machinery.

Areloger contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Areloger

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will give you the lowest possible dose, for the shortest length of time, to treat your symptoms. If your condition does not get better or you suffer from any side effects, tell your doctor. Your doctor should monitor your condition and treatment.

Use in adults and adolescents over 16 years of age
Flare-ups of osteoarthrosis: The recommended dose is 7.5 mg once daily. This may be increased by your doctor to 15 mg once daily if there has been no improvement.

Treatment of pain from rheumatoid arthritis or ankylosing spondylitis: The recommended dose is 15 mg once daily.

Your doctor may reduce your dose to 7.5 mg a day if your symptoms improve.

Never exceed a dose of 15 mg a day.

Kidney & liver impairment:
In dialysis patients with severe kidney failure, the recommended dose should not exceed 7.5 mg a day.

Patients with kidney or liver problems that are not severe can be given the normal recommended doses for adults as stated above.

Areloger are not recommended for use for patients with severe kidney failure who are not receiving dialysis or with severe liver failure.

Use in elderly:
If you are elderly your doctor may recommend a lower dose. The recommended dose for treatment of rheumatoid arthritis and ankylosing spondylitis is 7.5 mg once daily.

Use in children and adolescents:
Children and adolescents under the age of 16 years must not take Areloger.

Take Areloger orally as a single dose with water or another drink and together with a meal.

For Areloger 7.5 mg Tablets: The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

For Areloger 15 mg Tablets: The tablet can be divided into equal doses.

If you take more Areloger than you should
Contact your doctor or your nearest hospital emergency department. Take this leaflet and any tablets you still have with you.
You may have an allergic reaction (see section 4) or feel weak, drowsy, sick (nausea) or be sick (vomit), have stomach pains or bleeding in your stomach or bowel. More serious effects may be high blood pressure, kidney failure, liver problems, breathing problems, coma, fits (convulsions) or heart problems.

If you forget to take Areloger
If you forget to take a dose, take it as soon as you remember it unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Areloger
Do not to stop taking your medicine without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking this medicine and immediately contact your doctor or go to your nearest hospital emergency department if you get the following effects:

Uncommon (may affect up to 1 in 100 people)
- Skin reactions such as an itchy rash or swelling of the face, eyes, mouth, lips, tongue or throat which may cause difficulty swallowing or breathing
- Bleeding in the stomach or bowel which you may see as blood in your stools, black tar-like stools or if you are sick, it may contain red or dark blood particles that look like coffee grounds

Rare (may affect up to 1 in 1,000 people)

- An increase in infections which you may see as fevers, severe chills, sore throat or mouth ulcers (these may indicate you have a low number of white blood cells in your body)
- Potentially life threatening skin reactions such as large areas of red, blistering or peeling skin and bleeding of the lips, eyes, genitals or mouth (which may include Stevens-Johnson syndrome or toxic epidermal necrolysis)
- Raised, red itchy skin reaction (hives)
- An ulcer in the stomach or bowel. You may notice a bloated stomach, burning pain or tenderness in your stomach or bowel area, loss of appetite, feeling sick (nausea) with or without being sick (vomiting). You may also notice bleeding from the stomach or bowel

Very rare (may affect up to 1 in 10,000 people)

- Yellowing of your skin or whites of the eyes, dark urine, pale stools and generally feeling unwell (these may indicate you have serious problems with your liver)
- Producing little or no urine, pain or difficulty when passing urine, cloudy or dark urine, blood in the urine or lower back pain (these may indicate serious problems with your kidneys seen in patients with risk factors such as low blood volume, elderly, heart, kidney or serious liver problems)
- A tear in your stomach or bowel. You may have severe pain or notice bleeding from the stomach or bowel
- A severe reduction in white blood cells in your body. You may notice an increase in infections
- An extensive measles like rash across the body
- Blisters forming between the layers of skin, typically on the legs and arms, which may burst

Medicines such as meloxicam may be associated with a small increased risk of heart attack or stroke.

- If you have severe chest pain, which may move into the jaw and arm, feel sweaty or short of breath, these may be signs of a heart attack
- If you have numbness or weakness on one side of the body, notice that one side of the face is drooped, have problems talking or blurred or loss of vision, these may be signs of a stroke

Not known (frequency cannot be estimated from the available data)

- Serious allergic reactions, which may cause an itchy, raised red skin rash, swelling of the face, eyes, mouth, lips, tongue or throat which may cause difficulty swallowing or breathing, feeling faint or lightheaded, wheezing, collapse or loss of consciousness
- A distinctive cutaneous allergic reaction known as fixed drug eruption, that usually recurs at the same site(s) on re-exposure to the medication and may look like round or oval patches of redness and swelling of the skin, blistering (hives), itching.

Other side effects include:

Very common (may affect more than 1 in 10 people)

- Indigestion
- Nausea (feeling sick)
- Vomiting (being sick)
- Stomach pain
- Constipation
- Wind

- Diarrhoea

Common (may affect up to 1 in 10 people)
- Headache

Uncommon (may affect up to 1 in 100 people)
- Looking pale with headaches, shortness of breath when exercising or feeling abnormally tired (these may indicate you have a low number of red blood cells)
- Other non-serious allergic reactions, which may cause sneezing or itchy eyes
- Dizziness
- A spinning sensation (vertigo)
- Drowsiness
- Increased blood pressure
- Feeling flushed
- Inflammation of the stomach or bowel
- Burping
- High levels of potassium or sodium in the blood
- Sore mouth
- Changes to your kidney or liver function as seen on a blood test
- Swelling (fluid retention) especially of the feet or ankles
- Rash

Rare (may affect up to 1 in 1,000 people)
- Unexplained bruising or bleeding for longer than normal (these may indicate you have a low number of platelets in the blood)
- Changes to the blood as seen in a blood test
- Changes in your mood
- Nightmares
- Ringing in your ears
- Fast heart beats that feels like thumping in your chest (palpitations)
- Eyesight problems such as blurred vision or itchy, runny eyes (conjunctivitis)
- Chest tightness, shortness of breath or wheezing (you may have asthma particularly if you are allergic to other NSAIDs such as aspirin)
- Heartburn which may be a sign you have inflammation of the food pipe (oesophagitis)
- Swelling of the large bowel, which may cause pain, cramping and diarrhoea

Not known (frequency cannot be estimated from the available data)
- Skin sensitivity to light such as sunburn more easily
- Confusion
- Disorientation
- Pancreatitis (inflammation of the pancreas)
- Female infertility, delayed ovulation

Other side effects seen in other non-steroidal anti-inflammatory drugs (NSAIDs) but not yet seen in meloxicam
- Heart failure
- Other serious kidney problems

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Areloger

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Areloger contains

- The active substance is meloxicam. Each tablet contains 7.5 mg or 15 mg.

- The other ingredients are microcrystalline cellulose, pregelatinised maize starch, lactose monohydrate, maize starch, sodium citrate, colloidal anhydrous silica and magnesium stearate.

What Areloger looks like and contents of the pack

For Areloger 7.5 mg Tablets: Pale yellow, flat round tablets with a score line on one side.

For Areloger 15 mg Tablets: Pale yellow, flat round tablets with a break line on one side.

PVC/PVdC/Al blister packs of 7, 10, 14, 15, 20, 28, 30, 50, 60, 100, 140, 280, 300, 500 or 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
McDermott Laboratories Limited t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13

Manufacturer

McDermott laboratories Ltd t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

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Dublin Road, Loughrea, H62 FH90, Ireland

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This medicinal product is authorised in the Member States of the EEA under the following names:

Greece	Meloxicam / Mylan 15 mg Δισκία
Ireland	Areloger
Portugal	Meloxicam Mylan
Spain	Meloxicam MYLAN 7,5 mg and 15 mg Comprimidos EFG

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