

Package leaflet: Information for the patient

Melcam 7.5 mg Tablets

Melcam 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 Melcam is and what it is used for
2. What you need to know before you take Melcam
3. How to take Melcam
4. Possible side effects
5. How to store Melcam
6. Contents of the pack and other information

1. What Melcam is and what it is used for

Melcam contains the active substance meloxicam. Meloxicam belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). They are used to reduce inflammation and pain in the joints and muscles. This is what you get in arthritis and some other joint problems.

Melcam is used for the:

- short-term treatment of flare-ups of osteoarthritis (breakdown of the cartilage in joints)
- long-term treatment of
 - rheumatoid arthritis (joint inflammation)
 - ankylosing spondylitis (a chronic inflammation in the small joints between the spinal vertebrae, causing stiffness in the back, also known as Bechterew's Disease).

2. What you need to know before you take Melcam

Do not take Melcam if you:

- are allergic to meloxicam or any of the other ingredients of this medicine (listed in section 6)
- are allergic to acetylsalicylic acid or other anti-inflammatory medicines (NSAIDs), i.e. if you ever had any of the following signs after taking acetylsalicylic acid or other NSAIDs:
 - wheezing, chest tightness, breathlessness (asthma)
 - nasal blockage due to swellings in the lining in your nose (nasal polyps)
 - skin rashes/nettle rash (urticaria)
 - sudden skin or mucosal swelling, such as swelling around the eyes, face, lips, mouth or throat, possibly making breathing difficult (angioedema)
- have severe liver or kidney problems (e.g. decreased urine output)
- have severe heart failure
- have any kind of bleeding disorders
- have ulcers or bleeding in your stomach or gut (signs may be severe pain in your bowel or black stools or blood in the stool)
- have history of ulcers or bleeding in the stomach or gut (occurring at least twice)
- ever had bleeding in your brain
- ever had bleeding or perforation in the stomach or gut, related to previous NSAIDs therapy
- are in the last three months of pregnancy

- are a child or adolescent under 16 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Melcam if you:

- have a history of inflammation of the gullet (oesophagitis), inflammation of the stomach (gastritis) or a history of any other disease of the digestive tract, e.g. Crohn's Disease or ulcerative colitis
- have high blood pressure (hypertension)
- are elderly. You may have an increased risk for side effects.
- have heart, liver or kidney disease
- have high levels of sugar in the blood (diabetes mellitus)
- have reduced blood volume (hypovolaemia) which may occur if you have a serious blood loss or burn, surgery or low fluid intake
- have high levels of sodium or potassium in your blood.

Melcam is not appropriate if you require immediate relief from acute pain.

Melcam may hide the symptoms of infection (e.g. fever). If you think you may have an infection you should see your doctor.

Medicines such as Melcam 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 take more than the recommended dose. Do not take Melcam for longer than it is prescribed for you (see section 3 "How to take Melcam").

If you have heart problems, previous stroke or think that you might be at risk of these conditions you should discuss your treatment with your doctor. For example if you:

- have high blood pressure
- have high levels of sugar in the blood (diabetes mellitus)
- have high levels of cholesterol in the blood (hypercholesterolemia)
- are a smoker

If you have previously suffered from any symptoms of the digestive tract due to long term use of NSAIDs, seek medical advice immediately, especially if you are elderly. Your doctor may monitor your progress whilst on treatment.

Stop your treatment with Melcam immediately as soon as you notice bleeding (causing tar-coloured stools) or ulceration of your digestive tract (causing abdominal pain).

- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Melcam, 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 month of treatment.
- If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of meloxicam, you must not be re-started on meloxicam containing medicines such as Melcam at any time.
- If you develop a rash or these skin symptoms, stop taking Melcam, seek urgent advice from a doctor and tell him/her that you are taking this medicine.

Children and adolescents

Do not give this medicine to children and adolescents under the age of 16 years (see section "Do not take Melcam if you" above).

Other medicines and Melcam

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can cause problems if you take them with Melcam. These are:

- other non-steroidal anti-inflammatory drugs (NSAIDs), e.g. diclofenac or ibuprofen, including acetylsalicylic acid
- medicines which prevent blood clotting, such as warfarin, heparin, ticlopidine or novel oral anticoagulants (e.g. dabigatran, apixaban or rivaroxaban)
- medicines used to dissolve blood clots (thrombolytics)
- medicines to treat high blood pressure
- medicines to treat heart and kidney diseases
- corticosteroids (e.g. used against inflammation or allergic reactions)
- ciclosporin or tacrolimus - used after organ transplants, or for severe skin conditions, rheumatoid arthritis or nephrotic syndrome
- diuretic medicines ("water tablets")

Your doctor may monitor your kidney function if you are taking diuretics.

- medicine to treat high blood pressure (e.g. beta-blockers)
- lithium – used to treat mood disorders
- selective serotonin re-uptake inhibitors (SSRIs) – used in the treatment of depression (such as citalopram, sertraline, paroxetine)
- methotrexate - used to treat joint or skin problems or cancer
- cholestyramine - used to lower cholesterol levels
- medicines which may increase potassium levels in the blood, such as potassium salts
- deferasirox – a medicine to reduce chronic iron overload
- pemetrexed – to treat certain types of cancer.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

- If a pregnancy is established during use of Melcam, then the doctor is to be notified.
During the first 6 months of pregnancy your doctor may punctually prescribe you this medicine only if clearly necessary.
During the last three months of pregnancy, do not use this product, because Melcam can have serious effects on your child, in particular cardiopulmonary and renal effects, even with only one administration.
- This medicine is not recommended during breast-feeding. Ask your doctor or pharmacist for advice before taking this medicine.
- Melcam may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems to become pregnant.

Driving and using machines

Usually Melcam does not affect your ability to drive and use machines.

However, this medicine may cause side effects such as visual disturbances including blurred vision, dizziness, vertigo or other central nervous system disturbances (see section 4 "Possible side effects"). If any of these affect you, do not drive or use machines.

Melcam contains lactose monohydrate

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

3. How to take Melcam

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

The recommended dose is:

Melcam 7.5 mg Tablets:

Flare-ups of osteoarthritis

7.5 mg (one tablet) once a day. This may be increased to 15 mg (two tablets) once a day.

Rheumatoid arthritis

15 mg (two tablets) once a day. This may be reduced to 7.5 mg (one tablet) once a day.

Ankylosing spondylitis

15 mg (two tablets) once a day. This may be reduced to 7.5 mg (one tablet) once a day.

Melcam 15 mg Tablets:

Flare-ups of osteoarthritis

7.5 mg (half a tablet) once a day. This may be increased to 15 mg (one tablet) once a day.

Rheumatoid arthritis

15 mg (one tablet) once a day. This may be reduced to 7.5 mg (half a tablet) once a day.

Ankylosing spondylitis

15 mg (one tablet) once a day. This may be reduced to 7.5 mg (half a tablet) once a day.

Do not take more than 15 mg a day.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

Melcam 7.5 mg Tablets:

If any of the statements listed under the heading “Warnings and precautions” apply to you, your doctor may restrict your dose to 7.5 mg (one tablet) once a day.

Melcam 15 mg Tablets:

If any of the statements listed under the heading “Warnings and precautions” apply to you, your doctor may restrict your dose to 7.5 mg (half a tablet) once a day.

If you feel that the effect of Melcam is too strong or too weak, or if after several days you do not feel any improvement in your condition, talk to your doctor.

Method of administration

The tablet should be

- taken with food
- swallowed with water or another drink
- taken at about the same time each day.

Melcam 7.5 mg Tablets:

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Melcam 15 mg Tablets:

The tablet can be divided into equal doses.

If you take more Melcam than you should

If you have taken too many tablets, contact your doctor or a hospital immediately. Show them the pack or this leaflet.

Symptoms of an overdose are usually limited to lack of energy (lethargy), drowsiness, feeling sick (nausea), being sick (vomiting) and pain in the area of the stomach (epigastric pain). These symptoms

generally get better when you stop taking Melcam. You may suffer from bleeding of the stomach or intestines (gastrointestinal bleeding).
Severe poisoning may result in serious reaction.

If you forget to take Melcam

If you miss a dose of Melcam, simply carry on with the next dose as usual.
Do not take a double dose to make up for the forgotten dose.

If you stop taking Melcam

Do not stop treatment without talking to your doctor first.

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 consult a doctor or your nearest hospital immediately if you notice:

Any allergic (hypersensitivity) reactions, which may appear in the form of:

- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) which have been reported (see section 2)
- swelling of skin or mucosa, such as swelling around the eyes, face and lips, mouth or throat, possibly making breathing difficult, swollen ankles or legs (oedema of the lower limbs)
- shortness of breath or asthma attack
- inflammation of the liver (hepatitis). This can cause symptoms such as:
 - yellowing of the skin or the eyeballs (jaundice)
 - pain in the abdomen
 - loss of appetite.

Any side effects of the digestive tract, especially:

- bleeding (causing tar-coloured stools)
- ulceration of your digestive tract (causing abdominal pain).

Bleeding of the digestive tract (gastrointestinal bleeding), formation of ulcers or formation of a hole in the digestive tract (perforation) may sometimes be severe and potentially fatal, especially in elderly.

The following side effects can occur during treatment with Melcam:

Very common, may affect more than 1 in 10 people

- indigestion, feeling and being sick, stomach pain, constipation, flatulence, diarrhoea.

Common, may affect up to 1 in 10 people

- headache.

Uncommon, may affect up to 1 in 100 people

- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia)
- localised, non-life-threatening allergic reactions
- dizziness (light-headedness), vertigo (a feeling of spinning around), feeling sleepy
- increase in blood pressure
- flushing (temporary redness of the face and neck)
- bleeding in the stomach or gut
- mouth soreness (stomatitis)
- inflammation of the stomach (gastritis)
- eructation

- itchy skin, rash
- sudden skin or mucosal swelling, such as swelling around the eyes, face, lips, mouth or throat, possibly making breathing difficult (angioedema)
- momentary disturbance of liver function tests (e.g. raised liver enzymes like transaminases or an increase of the bile pigment bilirubin). Your doctor can detect these using a blood test.
- disturbance of laboratory tests investigating kidney (renal) function (e.g. raised creatinine or urea)
- sodium and water retention
- swelling caused by fluid retention (oedema), including swollen ankles/legs
- high levels of blood potassium which can cause abnormal heart rhythm.

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

- abnormal blood count, including abnormal differential blood count
- decreased number of white blood cells with increased risk of severe infection (leukopenia)
- reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- mood disorders
- nightmares
- visual disturbances including blurred vision, discharge from the eye with itching, redness and swelling (conjunctivitis)
- ringing in the ears (tinnitus)
- feeling your heartbeat
- asthma attacks (seen in people who are allergic to acetylsalicylic acid or other NSAIDs)
- inflammation of the large bowel which causes abdominal pain or diarrhoea (colitis)
- ulcers in the stomach or upper part of the small bowels (peptic/gastroduodenal ulcers)
- inflammation of the gullet (oesophagitis)
- severe blistering of the skin or peeling (Stevens-Johnson syndrome and toxic epidermal necrolysis)
- nettle rash (urticaria).

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

- severe reduction in number of white blood cells which makes infections more likely (agranulocytosis) especially in patients who take Melcam together with other medicines that are potentially inhibitory, depressant or destructive to a component of the bone marrow (myelotoxic drugs). This can cause symptoms such as sudden fever, sore throat or infections.
- a hole in the wall of the stomach or gut (perforation)
- inflammation of the liver (hepatitis) with possible symptoms such as nausea, loss of appetite, pain in the abdomen and yellowing of the skin or whites of the eyes
- blistering reactions of the skin (bullous reactions) and erythema multiforme. Erythema multiforme is a serious allergic skin reaction causing spots, red welts or purple or blistered areas. It can also affect the mouth, eyes and other moist body surfaces.
- acute kidney failure in particular in patients with risk factors such as heart disease, diabetes or kidney disease.

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

- serious allergic reaction which may cause difficulty in breathing or dizziness (anaphylactic/anaphylactoid reactions)
- confusion, disorientation
- heart failure has been reported in association with NSAID treatment, which can cause shortness of breath or ankle swelling
- rashes caused by sensitivity and exposure to sunlight (photosensitivity reactions)
- pancreatitis (inflammation of the pancreas).

Medicines such as Melcam may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Side effects caused by non-steroidal anti-inflammatory medicines (NSAIDs), but not yet seen after taking meloxicam

Changes to the kidney structure resulting in acute kidney failure:

- very rare cases of kidney inflammation (interstitial nephritis)
- death of some of the cells within the kidney (acute tubular or papillary necrosis)
- protein in the urine (nephrotic syndrome with proteinuria).

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Melcam

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 the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Melcam contains

- The active substance is meloxicam.
Each tablet contains 7.5 mg meloxicam.
Each tablet contains 15 mg meloxicam.
- The other ingredients are maize starch, pregelatinized maize starch, colloidal anhydrous silica, sodium citrate, lactose monohydrate, microcrystalline cellulose, magnesium stearate.

What Melcam looks like and contents of the pack

Melcam are pale yellow coloured, round, flat bevelled uncoated tablets with central break-line on one side and plain on the other side.

Melcam are packed in blisters and available in carton boxes with 10, 20, 30, 50, 60 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Hexal A/S, Kanalholmen 8 – 12, 2650 Hvidovre, Denmark.

Rowa Pharmaceuticals Ltd., Newtown, Bantry, Co. Cork, Ireland.

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

Austria	Meloxicam Hexal 7,5 mg - Tabletten
Denmark	Camoxip

Ireland	Melcam 7.5 mg Tablets
	Melcam 15 mg Tablets
Spain	MELOXICAM SANDOZ 7,5 mg comprimidos EFG
	MELOXICAM SANDOZ 15 mg comprimidos EFG

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