

Meloxicam 15 mg PIL

Size: 200 x 550mm

200mm

Package leaflet: Information for the user  
Mobicam 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 Mobicam is and what it is used for.
2. What you need to know before you take Mobicam tablets.
3. How to take Mobicam tablets.
4. Possible side effects.
5. How to store Mobicam tablets.
6. Contents of the pack and other Information.

**1. What Mobicam is and what it is used for**  
Mobicam contains the active substance meloxicam. Meloxicam belongs to the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to reduce inflammation and pain in joints and muscles. Mobicam is indicated in adults and adolescents above 16 years.

Mobicam tablets are used for:

- Short-term treatment of flare ups of osteoarthritis
- Long-term treatment
  - o rheumatoid arthritis
  - o ankylosing spondylitis (also known as Bechterew's Disease)

**2. What you need to know before you take Mobicam tablets**

**Do not take Mobicam if**

- You are in the last three months of your pregnancy.
- You are a child or adolescent under the age of 16 years.
- You are allergic (have hypersensitivity) to meloxicam. You are allergic (have hypersensitivity) to aspirin or other anti-inflammatory medicines (NSAIDs).
- You are allergic (have hypersensitivity) to any of the other ingredients of Mobicam (See section 6 "Further information" for a list of other ingredients).
- You have suffered from any of the following signs after taking aspirin or other NSAIDs:
  - o wheezing, chest tightness, breathlessness (asthma)
  - o nasal blockage due to swellings in the lining in your nose (nasal polyps)
  - o skin rashes/itchy rash (urticaria)
- Sudden skin or mucosal swelling, such as swelling around the eyes, face, lips, mouth or throat, possibly making breathing difficult (angioneurotic oedema).
- Following previous therapy with NSAIDs you had history of
  - o bleeding in your stomach or intestines
  - o holes (perforations) in your stomach or intestines
- You have ulcers or a bleeding in your stomach or intestines
- Recently you have or had history of stomach or peptic ulcers or bleeding (ulceration or bleeding occurring at least twice)
- You have severely impaired liver function
- You have non dialysed severe kidney failure
- You have recently had bleeding in the brain (cerebrovascular bleeding)
- You have any kind of bleeding disorders
- You have severe heart failure
- You have intolerance to some sugars as this product contains lactose (see also "Important information about some of the ingredients of Mobicam")

If you are unsure whether any of the above apply to you, please contact your doctor.

**Warnings and Precautions**  
Medicines such as Mobicam may be associated with a small increased risk of heart attack (myocardial infarction) or stroke (apoplexy). Any risk is more likely with high doses and prolonged treatment. Do not take more than the recommended dose. Do not take Mobicam for longer than it is prescribed for you (see section 3 "How to take Mobicam").

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 or pharmacist. For example if you:

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

Potentially life – threatening skin rashes (Stevens-Johnson syndrome and toxic epidermal necrolysis) have been reported with the use of Meloxicam, 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 Meloxicam, you must not be re-started on Meloxicam at any time.

If you develop severe allergic reactions, you should discontinue Mobicam at first appearance of skin rash, lesions of soft tissues (mucosal lesions), or any other sign of allergy, and contact your doctor.

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

Mobicam is not appropriate if you require immediate relief from acute pain.  
Mobicam may hide the symptoms of infection (e.g. fever). If you think you may have an infection you should see your doctor.

**Precautions for use**

As it will be necessary to adjust the treatment, it is important to ask your doctor's advice before you take Mobicam in case of:

- history of inflammation of the gut (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
- high blood pressure (hypertension)
- older age
- heart, liver or kidney disease
- high levels of sugar in the blood (diabetes mellitus)
- reduced blood volume (hypovolaemia) which may occur if you have a serious blood loss or burns, surgery or low fluid intake
- intolerance to some sugars diagnosed by your doctor as this product contains lactose
- high potassium levels in the blood previously diagnosed by your doctor

Your doctor will need to monitor your progress whilst on treatment.

**Other medicines and Mobicam**

As Mobicam may affect or be affected by other medicines, please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular please tell your doctor or pharmacist if you are taking/have taken, or are using any of the following:

- other NSAIDs
- medicines which prevent blood clotting (thrombolytics)
- medicines to treat heart and kidney diseases
- corticosteroids (e.g. used against inflammation or allergic reactions)
- cyclosporin – used after organ transplants, or for severe skin conditions, rheumatoid arthritis or nephrotic syndrome
- any diuretic medicine ("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
- methotrexate – used to treat tumours or severe uncontrolled skin conditions and active rheumatoid arthritis
- cholestyramine – used to lower cholesterol levels

if you are a woman who uses an intrauterine contraceptive device (IUD), usually known as a coil.

**If in doubt, ask your doctor or pharmacist**

**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 or pharmacist for advice before taking this medicine.

**Fertility**

Mobicam 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.

**Pregnancy**

If pregnancy is established during use of meloxicam, then the doctor is to be notified. During the first 6 months of pregnancy your doctor may punctually prescribe you this medical product if necessary. During the last three months of pregnancy, do not use this product because meloxicam can have serious effects on your child, in particular cardiopulmonary and renal effects, even with only one administration.

**Breast feeding**

Mobicam tablets must not be taken if you are breast feeding.

**Driving and using machines**

Mobicam tablets may cause visual disturbances including blurred vision, drowsiness, dizziness, vertigo or other central nervous system disturbances. If affected do not drive or operate machinery.

**Mobicam tablets contain lactose**

Your medicine contains small quantities of milk sugar known as lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**3. How to take Mobicam tablets**

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:

(For flare-ups of osteoarthritis):

The recommended dose for the treatment of osteoarthritis is 7.5 mg/day (i.e. one tablet of 7.5 mg once daily or half a tablet of 15 mg once daily). This may be increased by your doctor to 15 mg/day (i.e. two tablets of 7.5 mg once daily, or one tablet of 15 mg once daily) if the effect is too weak.

(For rheumatoid arthritis and ankylosing-spondylitis):

The recommended dose for pain from rheumatoid arthritis and ankylosing spondylitis is 15 mg/day (i.e. two tablets of 7.5 mg once daily or one tablet of 15 mg once daily). Your doctor may reduce the dose to 7.5 mg per day (i.e. one tablet of 7.5 mg once daily or half of 15 mg once daily) depending on your response to treatment.

Never exceed the recommended maximum dose of 15 mg a day.

Method of administration

Oral use

The tablets should be swallowed with water, or another liquid, during a meal.

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.

**Use in Children and Adolescents**

Children and adolescents under the age of 16 years must not take Mobicam tablets.

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

**If you take more Mobicam Tablets than you should**

Whether you have taken too many tablets or suspect an overdose, contact your doctor or go to your nearest hospital immediately. Symptoms following acute NSAID overdose are usually limited to:

- Lack of energy (lethargy)
- Drowsiness
- Feeling sick (nausea) and being sick (vomiting)
- Pain in the area of the stomach (epigastric pain)

These symptoms generally get better when you stop taking Mobicam. You may suffer from bleeding of the stomach or intestines (gastrointestinal bleeding).

Severe poisoning may result in serious drug reaction (see section 4.)

- High blood pressure (hypertension)
- Acute kidney (renal) failure
- Liver (hepatic) dysfunction
- Reduction/fluttering or standstill of breathing (respiratory depression)
- Loss of consciousness (coma)
- Seizures (convulsions)
- Collapse of the blood circulation (cardiovascular collapse)
- Standstill of the heart (cardiac arrest)
- Immediate allergic (hypersensitivity) reactions, including:
  - o Fainting
  - o Shortness of breath
  - o Skin reactions

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**If you forget to take Mobicam Tablets**

If you forget to take a dose, do so as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten dose.  
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.

**Serious side effects**

If any of the following happen, stop taking Mobicam Tablets and tell your doctor immediately or go to the casualty department at your nearest hospital immediately:

- skin reactions, such as itching (pruritus), blistering or peeling of the skin, which can be severe (Steven-Johnson Syndrome and toxic epidermal necrolysis), lesions of soft tissues (mucosal lesions) or 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.
- 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:
  - o yellowing of the skin or the eyeballs (jaundice)
  - o pain in the abdomen
  - o 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.

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.

If affected by visual disturbances do not drive or operate machinery.

General side effects of non-steroidal anti-inflammatory medicines (NSAIDs)

The use of some non-steroidal anti-inflammatory drugs (NSAIDs) may be associated with a small increased risk of occlusion of arterial vessels (arterial thrombotic events), e.g. heart attack (myocardial infarction) or stroke (apoplexy), particularly at high doses and in long term treatment.

Fluid retention (oedema), high blood pressure (hypertension) and heart failure (cardiac failure) have been reported in association with NSAID treatment.

The most commonly-observed side effects affect the digestive tract (gastrointestinal events):

- ulcers of the stomach and upper part of the small bowels (peptic/gastroduodenal ulcers)
- a hole in the wall of the bowels (perforation) or bleeding of the digestive tract (sometimes fatal, particularly in the elderly)

The following side effects have been reported after NSAID administration:

- feeling sick (nausea) and being sick (vomiting)
- loose stools (diarrhoea)
- flatulence
- constipation
- indigestion (dyspepsia)
- abdominal pain
- tar-coloured stool due to bleeding in the digestive tract (melaena)
- vomiting of blood (haematemesis)
- flushing (temporary redness of the face and neck)
- inflammation with building of ulcers in the mouth (ulcerative stomatitis)
- worsening of inflammation of the digestive tract (e.g. exacerbation of colitis or Crohn's disease)

Less frequently, inflammation of the stomach (gastritis) has been observed.

Side effects of Meloxicam - the active substance of Mobicam.

**Other side effects**

Tell your doctor if you notice any of the following:

*Very common: may affect more than 1 in 10 people*

- indigestion (dyspepsia)
- feeling sick (nausea) and being sick (vomiting)
- abdominal pain
- constipation
- flatulence
- loose stools (diarrhoea)

*Common: may affect up to 1 in 10 people*

headache

*Uncommon: may affect up to 1 in 100 people*

- dizziness (light-headedness)
- a feeling of dizziness or spinning (vertigo)
- somnolence (drowsiness)
- anaemia (reduction of the concentration of the red blood pigment haemoglobin)
- increase in blood pressure (hypertension)
- flushing (temporary redness of the face and neck)
- sodium and water retention
- increased potassium levels (hyperkalaemia). This can lead to symptoms such as:
  - o changes to your heartbeat (arrhythmias)
  - o palpitations (when you feel your heartbeat more than usual)
  - o muscle weakness
- eructation
- inflammation of the stomach (gastritis)
- bleeding of the digestive tract
- inflammation of the mouth (stomatitis)
- immediate allergic (hypersensitivity) reactions
- itching (pruritus)
- skin rash
- swelling caused by fluid retention (oedema), including swollen ankles/legs (oedema of the lower limbs)
- sudden skin or mucosal swelling, such as swelling around the eyes, face, lips, mouth or throat, possibly making breathing difficult (angioneurotic oedema)
- 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)

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

- mood disorders
- nightmares
- abnormal blood count, including:
  - o abnormal differential blood count
  - o decreased number of white blood cells (leucocytopenia)
  - o decreased number of blood platelets (thrombocytopenia)

These side effects may lead to increased risk of infection and symptoms such as bruising or nosebleeds.

- ringing in the ear (tinnitus)
- feeling your heartbeat (palpitations)
- ulcers of the stomach or upper part of the small bowels (peptic/gastroduodenal ulcers)
- inflammation of the gut (oesophagitis)
- onset of asthma attacks (seen in people who are allergic to aspirin or other NSAIDs)
- severe blistering of the skin or peeling (Stevens-Johnson Syndrome and toxic epidermal necrolysis)
- nettle rash (urticaria)
- visual disturbances including:
  - o blurred vision
  - o conjunctivitis (inflammation of the eyeball or eyelids)
  - o inflammation of the large bowel (colitis)

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

- 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.
- inflammation of the liver (hepatitis). This can cause symptoms such as:
  - o yellowing of the skin or the eyeballs (jaundice)
  - o pain in the abdomen
  - o loss of appetite
- acute failure of the kidneys (renal failure) in particular in patients with risk factors such as heart disease, diabetes or kidney disease.
- a hole in the wall of the bowels (perforation)

*Not known: frequency cannot be estimated from the available data*

- confusion
- disorientation
- shortness of breath and skin reactions (anaphylactic/anaphylactoid reactions) rashes caused by exposure to sunlight (photosensitivity reactions)
- heart failure (cardiac failure) has been reported in association with NSAID treatment
- complete loss of specific types of white blood cells (agranulocytosis), especially in patients who take Mobicam together with other drugs that are potentially inhibitory, depressant or destructive to a component of the bone marrow (myelotoxic drugs). This can cause:
  - o sudden fever
  - o sore throat
  - o infections

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

- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPR 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 Mobicam tablets**

Keep out of the sight and reach of children. Do not use Mobicam tablets after the expiry date stated on the carton/ label after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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

**6. Contents of the pack and other information**

**What Mobicam contains**

The active substance in Mobicam tablets is meloxicam. Mobicam Tablets contain 15 mg of meloxicam. The other ingredients are: microcrystalline cellulose, pregelatinised maize starch, lactose monohydrate, maize starch, sodium citrate, colloidal anhydrous silica and magnesium stearate.

**What Mobicam looks like and contents of the pack**

Mobicam tablets are pale yellow, round tablets with a score line on one side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses. PVC/PPVC and hard tempered Aluminium foil. Cartons of 7, 10, 14, 15, 20, 28, 30, 50, 60, 100, 140, 280, 300, 500 or 1000 tablets (not all the pack sizes may be marketed).

**The marketing authorisation holder and manufacturer**

**Marketing authorisation holder**

Ranbaxy Ireland Ltd., Spallfield, Cork Road, Cashel, Co. Tipperary, Ireland

**Manufacturer**

Chanelle Medical Limited, IDA Industrial Estate, Loughrea, Co. Galway, Ireland

**Distributed by**

Pinewood Laboratories Limited, Ballymacarby, Clonmel, Co. Tipperary, Ireland

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

Czech Republic- Melobax 15mg tablet

Ireland- Mobicam 15mg Tablets

Latvia- Melobax 15mg tablets

Lithuania- Melobax 15mg tablets

Poland- Melobax 15mg tablet

Slovak- Melobax 15 mg tablet

Spain- Melobax 15 mg tablet

**This leaflet was last approved in:** September 2014

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