

**PACKAGE LEAFLET: INFORMATION FOR THE USER****Meloxicam Chanelle Medical 7.5 mg Tablets****Meloxicam Chanelle Medical 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.

**In this leaflet:**

1. What Meloxicam Chanelle Medical tablets are and what they are used for.
2. What you need to know before you take Meloxicam Chanelle Medical
3. How to take Meloxicam Chanelle Medical tablets.
4. Possible side effects.
5. How to store Meloxicam Chanelle Medical tablets.
6. Contents of the pack and other information

**1. What Meloxicam Chanelle Medical tablets are and what they are used for**

Meloxicam contains the active substance meloxicam. Meloxicam belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) which are used to reduce inflammation and pain in joints and muscles.

Meloxicam Chanelle Medical tablets is used for:

- short-term treatment of flare-ups of osteoarthritis
- long-term treatment of
  - rheumatoid arthritis
  - ankylosing spondylitis

**2. What you need to know before you take Meloxicam Chanelle Medical****Do not take Meloxicam Chanelle Medical tablets:**

- during the last three months of pregnancy.
- children and adolescents under 16 years of age.
- if you are allergic to meloxicam, aspirin or other anti-inflammatory medicines (NSAIDs)
- if you are allergic to any of the other ingredients of this medicine (listed in section 6)
- any of the following signs after taking aspirin 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 (angioneurotic oedema)
- after previous therapy with NSAIDs and history of
  - bleeding in your stomach or intestines
  - holes (perforations) in your stomach or intestines
- ulcers or bleeding in your stomach or intestines
- recent or history of stomach or peptic ulcers or bleeding (ulceration or bleeding occurring at least twice)
- severely impaired liver function
- non dialysed severe kidney failure
- recent bleeding in the brain (cerebrovascular bleeding)
- any kind of bleeding disorders
- severe heart failure

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

**Warnings and precautions**

**Warnings**

Medicines such as Meloxicam Chanelle Medical 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 Meloxicam Chanelle Medical for longer than it is prescribed for you (see section 3 "How to take Meloxicam Chanelle Medical").

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

Stop your treatment with Meloxicam Chanelle Medical 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 Meloxicam Chanelle Medical, 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 Chanelle Medical, you must not be re-started on Meloxicam Chanelle Medical at any time.

If you develop a rash or these skin symptoms, stop taking Meloxicam Chanelle Medical, seek urgent advice from a doctor and tell him that you are taking this medicine.

Meloxicam Chanelle Medical is not appropriate, if you require immediate relief from acute pain.

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

**Take special care with Meloxicam Chanelle Medical tablets and talk to your doctor:**

- if you have a history of asthma
- if you have to take a blood or urine test, always mention that you are taking meloxicam
- 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).

**Precautions for use**

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

- 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
- 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 burn, 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 Meloxicam Chanelle Medical**

As Meloxicam Chanelle Medical may affect or be affected by other medicines, tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- medicines which break down blood clots (thrombolytics)
  - medicines to treat heart and kidney diseases
  - corticosteroids (e.g. used against inflammation or allergic reactions)
  - cyclosporin/ tacrolimus – 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
  - deferasirox - used to treat ongoing high levels of iron in the body
  - pemetrexed - used to treat tumours
  - oral antidiabetics (sulphonylureas, nateglinide) (used to treat diabetes. Your doctor should carefully monitor your blood sugar level for hypoglycaemia)

The following medicinal products may promote elevated concentration of potassium (K+) in the blood when co-administered with Meloxicam:

- potassium salts,
- potassium-sparing diuretics,
- angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor antagonists,
- non-steroidal anti-inflammatory drugs,
- (low molecular-weight or unfractionated) heparins,
- cyclosporin, tacrolimus
- trimethoprim.

The onset of adverse events may depend on whether there are associated factors.

If in doubt, ask your doctor or pharmacist.

### **Pregnancy, breast-feeding and fertility**

#### **Pregnancy**

If a pregnancy is established during use of Meloxicam Chanelle Medical, then the doctor is to be notified.

Do not take Meloxicam Chanelle Medical if you are in 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 and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Meloxicam Chanelle Medical 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, Meloxicam Chanelle Medical 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**

This product is not recommended during breast-feeding.

Ask your doctor or pharmacist for advice before taking this medicine.

#### **Fertility**

Meloxicam Chanelle Medical 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**

Visual disturbances, including blurred vision, dizziness, drowsiness, vertigo or other central nervous system disturbances may occur with this product. If affected do not drive or operate machinery.

#### **Meloxicam Chanelle Medical contains milk sugar (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 Meloxicam Chanelle Medical tablets

Always take Meloxicam Chanelle Medical tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

#### Flare-ups of osteoarthritis:

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

#### Rheumatoid arthritis:

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

#### Ankylosing spondylitis:

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

#### Method of administration

Oral use

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

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.  
The tablet can be divided into equal doses

Do not exceed the recommended maximum dose of 15 mg a day.

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.

#### Elderly Patients

If you are elderly, the recommended dose for long-term treatment for rheumatoid arthritis and ankylosing spondylitis is 7.5mg once a day.

#### Patients who are at increased risk of adverse reactions

If you have a history of gastrointestinal disease or have increased risk of cardiovascular disease, your doctor will start treatment at a dose of 7.5 mg per day.

#### Renal insufficiency

If you are a dialysis patient with severe kidney failure, your dose should not exceed 7.5mg per day. In patients with mild to moderate renal impairment, no dose reduction is necessary.

#### Liver failure

In patients with mild to moderate hepatic impairment, a dose reduction is not necessary.

#### Use in children and adolescents

**Meloxicam Chanelle Medical should not be given to children and adolescents under 16 years of age.**

If you feel that the effect of Meloxicam Chanelle Medical 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 Meloxicam Chanelle Medical 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 Meloxicam Chanelle Medical. 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/flattening 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:
  - fainting
  - shortness of breath
  - skin reactions

**If you forget to take Meloxicam Chanelle Medical tablets:**

Do not take a double dose to make up for a forgotten dose. Just take the next dose at the usual time.

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

**4. Possible side effects**

Like all medicines, Meloxicam Chanelle Medical tablets can cause side effects, although not everybody gets them

**Stop taking Meloxicam Chanelle Medical and consult a doctor or your nearest hospital immediately if you notice:**

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

- skin reactions, such as itching (pruritus), blistering or peeling of the skin, which can be potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis), lesions of soft tissues (mucosal lesions) or erythema multiforme (see section 2). 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:
  - 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.

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)
- 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 Meloxicam Chanelle Medical**

##### **Very common: May affect more than 1 in 10 people**

- gastrointestinal adverse events such as 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:

- changes to your heartbeat (arrhythmias)
- palpitations (when you feel your heartbeat more than usual)
- 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:
  - abnormal differential blood count
  - decreased number of white blood cells (leucocytopenia)
  - 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 gullet (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:
  - blurred vision

- conjunctivitis (inflammation of the eyeball or eyelids)
- 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:
  - yellowing of the skin or the eyeballs (jaundice)
  - pain of the abdomen
  - 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**

- pancreatitis (inflammation of the pancreas)
- 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 Meloxicam Chanelle Medical together with other drugs that are potentially inhibitory, depressant or destructive to a component of the bone marrow (myelotoxic drugs). This can cause:
  - sudden fever
  - sore throat
  - infections
- infertility in women, delayed ovulation.
- 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.

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

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)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

**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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Meloxicam Chanelle Medical tablets**

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 strip and outer carton. The expiry date refers to the last day of that month.

This medicinal product 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 to protect the environment.

**6. Contents of the pack and other information****What Meloxicam Chanelle Medical tablets contain:**

The active substance is:



- meloxicam
- one tablet contains 7.5 mg meloxicam.
- one tablet contains 15 mg meloxicam.

The other ingredients are:

- microcrystalline cellulose
- pregelatinised maize starch
- lactose monohydrate
- maize starch
- sodium citrate
- colloidal anhydrous silica
- magnesium stearate

**What Meloxicam Chanelle Medical tablets look like and contents of the pack:**

Meloxicam Chanelle Medical tablets are pale yellow, round tablets with a score on one side.

Meloxicam Chanelle Medical 15 mg Tablets

The tablet can be divided into equal doses.

**Pack sizes:** 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 and Manufacturer:**

Marketing Authorisation Holder:  
Chanelle Medical Unlimited Company

Manufacturer:  
Chanelle Medical Unlimited Company  
Loughrea  
Co. Galway  
Ireland

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

DENMARK	Meloxicam Chanelle Medical Tablette 7,5 mg
DENMARK	Meloxicam Chanelle Medical Tablette 15 mg
FINLAND	Meloxicam Orion 7.5 mg Tabletti
FINLAND	Meloxicam Orion 15 mg Tabletti
IRELAND	Meloxicam Chanelle Medical 7.5 mg Tablets
IRELAND	Meloxicam Chanelle Medical 15 mg Tablets
UK	Meloxicam 7.5 mg Tablets
UK	Meloxicam 15 mg Tablets

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