

**Package leaflet: Information for the user**  
**Meloxicam Ranbaxy 7.5 mg and 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.

**What is in this leaflet:**

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

**1. What Meloxicam Ranbaxy is and what it is used for**

Meloxicam belongs to the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs are commonly used for the treatment of pain and to reduce inflammation in muscles and joints

Meloxicam Ranbaxy tablets are used for:

- Short-term treatment of flare ups of osteoarthritis (joint disease caused by the breakdown and loss of the cartilage of joints).
- Long-term treatment of other painful joint conditions such as rheumatoid arthritis and ankylosing spondylitis. Rheumatoid arthritis is a chronic disease marked by stiffness and inflammation of the joints, weakness, loss of mobility, and deformity of joints. Ankylosing spondylitis involves pain and inflammation of the spine.

**2. What you need to know before you take Meloxicam Ranbaxy tablets**

**Do not take Meloxicam Ranbaxy if**

- You are allergic to meloxicam or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, swelling of face, lips, or hands/feet, or breathing difficulties.
- You are in the last three months (third trimester) of your pregnancy or breast-feeding.
- You have previously had an allergic reaction, to other NSAIDs or to acetylsalicylic acid (medicine used in pain, inflammation and fever).

- You have suffered from asthma like wheezing, swelling of skin or hives (urticaria) after taking NSAIDs in the past.
- You have a blocked nose or difficulty in breathing through your nose after taking NSAIDs or aspirin in the past. These may be due to a fleshy growth in the nose called nasal polyps.
- You have an ulcer of the stomach or intestine (commonly called peptic ulcer), or have had them repeatedly in the past.
- You have bleeding in your stomach or intestine (gastrointestinal bleeding), any other bleeding disorder or had bleeding inside the brain (cerebrovascular bleeding).
- You have had gastrointestinal bleeding or perforation with the use of NSAID therapy at any time in the past
- You have severe problems with your liver
- You have severe problems with your kidney(s) and are not on dialysis
- You suffer from severe heart failure (heart failure is a condition where your heart fails to pump blood strongly enough to supply all the blood needed throughout the body).

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

### **Warnings and Precautions**

Talk to your doctor or pharmacist before taking Meloxicam Ranbaxy tablets if

- You are planning to get pregnant
- You are undergoing tests for infertility
- You have had a peptic ulcer, inflammation of the food pipe (oesophagitis) and/or stomach (gastritis)
- You have had digestive problems or diseases of the gastrointestinal tract (like Ulcerative colitis or Chron's disease; characterised by frequent loose stools with/ without blood, along with pain in the lower part of the abdomen) [see Possible side effects]
- You suffer from high blood pressure. Your blood pressure will be monitored before starting therapy with this medicine and regularly thereafter
- You had history of high blood pressure and/or mild to moderate heart failure as fluid accumulation and swelling have been reported.
- You develop any unusual abdominal symptoms (gastrointestinal bleeding) especially in the initial stage of treatment
- You have hypovolaemia (reduced blood volume) which may occur if you have serious blood loss or burns, surgery or low fluid intake.
- You suffer from a group of brain dysfunctions related to disease of blood vessels supplying the brain e.g. stroke
- You suffer from problems with your kidney(s). Your doctor will monitor your kidney functions regularly in case if you are at risk of developing kidney problems. Your doctor will not increase the dose of meloxicam by more than 7.5 mg if you are in last stage of kidney failure and on haemodialysis.
- You are elderly, fragile or weakened.

The chances of developing bleeding inside the stomach and gut, ulcers and perforation is higher with high dose of NSAID therapy, history of ulcer particularly with bleeding and perforation and in the elderly. Your doctor will keep you on lower doses of this medicine and give other protective agents. If you develop these conditions while taking this medicine, your doctor will advise you to stop taking this medicine.

While taking this medicine, you may be diagnosed with high sodium, potassium levels and/or water retention.

Medicines such as Meloxicam Ranbaxy tablets 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, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

You should not take more than a total quantity of 15 mg of Meloxicam Ranbaxy tablets in a day.

While taking this medicine if you develop abnormal increase in liver and kidney enzyme, your doctor may stop your treatment if it is significant and persistent.

#### Skin reaction

- Potentially life-threatening skin rashes (exfoliative derlatitis, Stevens-Johnson syndrome, 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 early in the course of therapy (within the first weeks). However the onset of the reaction occurring in the majority of cases 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 at any time.

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

Please consult your doctor, even if these statements were applicable to you at any time in the past.

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

## **Other medicines and Meloxicam Ranbaxy**

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

Meloxicam Ranbaxy tablets should not be taken with:

- Other non-steroidal anti-inflammatory drugs (NSAIDs like ibuprofen, aspirin, diclofenac, ketorolac, naproxen, indomethacin; “pain killers”)
- Blood thinning medicines such as oral anticoagulants (e.g. warfarin, coumarin), anti-platelet drugs (e.g. clopidogrel, ticlopidine), other anticoagulants (e.g. heparin, enoxaparin, dalteparin) and thrombolytic agents (e.g. streptokinase, urokinase, tPA). The concomitant use of NSAIDs and anticoagulants or heparin administered in elderly or at curative dose is not recommended.
- Lithium (used for treatment of mental illnesses)
- Methotrexate, especially when taken in doses more than 15 mg per week (a medicine used for immunosuppression and treatment of cancers)
- Cholestyramine (a lipid lowering medicine)
- Glucocorticoids (used to treat various conditions including rheumatism, arthritis, allergic conditions, certain skin diseases, asthma or certain blood disorders).

Meloxicam Ranbaxy tablets should be used with caution together with:

- Diuretics (commonly known as ‘water tablets’ e.g. furosemide, hydrochlorothiazide) - Taking these with your Meloxicam can lead to kidney problems especially if you are dehydrated and have not been taking adequate fluids.
- Medicines used for treating high blood pressure such as ACE inhibitors (e.g. ramipril, lisinopril) and angiotensin II receptor blockers (e.g. losartan, candesartan) and beta blockers (e.g. atenolol, metoprolol) - Taking these with Meloxicam can lead to loss of blood pressure lowering effect and kidney problems. It may also require monitoring of your kidney function. You must keep yourself well hydrated with adequate fluid intake when on treatment with these medicines together. Caution is required especially in elderly.
- Calcineurin inhibitors (medicines used for immunosuppression and treatment of cancers) e.g. Cyclosporine, tacrolimus
- Selective serotonin reuptake inhibitors (medicines used in certain brain problems) e.g. citalopram, fluoxetine, sertraline.
- Intra-uterine devices for birth control (IUCD e.g. coils) used by women- Use of meloxicam may lead to failure of the contraceptive effects.

Meloxicam Ranbaxy tablets should not be taken together with anticoagulants, diuretics or lithium preparations without doctor’s instructions.

If you are having blood or urine tests, please always mention to your doctor that you take Meloxicam Ranbaxy tablets.

## **Pregnancy and Breast feeding**

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.

**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**

Meloxicam Ranbaxy tablets must not be taken if you are breast feeding.

### **Driving and using machines**

Meloxicam Ranbaxy tablets may cause visual disturbances, drowsiness and/or dizziness. These may affect your ability to drive and use machines. Make sure you know how you react to Meloxicam Ranbaxy tablets before you drive, use machines, or engage in any other activity that could be dangerous if you are not alert.

### **Meloxicam Ranbaxy tablets contain lactose**

Your medicine contains small quantities of an inactive ingredient 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 Meloxicam Ranbaxy 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 for Meloxicam Ranbaxy Tablets is given below. Each person has his/her own needs.

Short-term treatment (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.

Long-term treatment (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 tablet of 15 mg once daily) depending on your response to treatment.

Never exceed a dose of 15 mg a day.

Elderly patients and patients with increased risk of side effects:

If you are elderly your doctor may recommend a lower dose.

### **Use in Children and Adolescents**

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

### **Patients with kidney disease/on kidney dialysis and patients with liver disease**

Your dose may be different in case you have a problem with your liver and/or kidney(s). In haemodialysis patients with severe kidney failure, dosage should not exceed one tablet of 7.5 mg a day.

Meloxicam Ranbaxy tablets should be taken as a single daily dose with water or another liquid and together with a meal. Your doctor will give you lowest effective dose for shortest duration required to control symptoms of your illness. This will help you to minimize the side effects caused by this medicine.

Change or cessation of treatment should always take place after discussion with your doctor.

### **If you take more Meloxicam Ranbaxy Tablets than you should**

If you accidentally take more Meloxicam Ranbaxy Tablets than your prescribed dose, you may feel sleepy, tired, or may feel or be sick (suffer from nausea or vomiting) or have pain in the abdomen. Contact your nearest hospital casualty department or tell your doctor immediately. Take this leaflet and any tablets you still have with you.

### **If you forget to take Meloxicam Ranbaxy 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.

The following side effects have been reported:

### **Serious side effects**

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

- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see section 2). This has been reported rarely.
- serious allergic reaction which causes difficulty in breathing or dizziness
- severe condition of the skin that may affect the mouth and other parts of the body manifested by red, often itchy spots. The spots may blister or may progress to form raised, red, pale-centered marks.
- severe blistering of the skin or peeling, swelling around the eyes, lips and face and rashes caused by exposure to sunlight.

These are very serious side effects. If you have them you may have had a serious allergic reaction or other type of reaction to Meloxicam Ranbaxy. You may need urgent medical attention or hospitalization.

### **Other side effects**

Tell your doctor if you notice any of the following:

*These side effects have been reported very commonly (may affect more than 1 in 10 people)*

- nausea (feeling sick), vomiting (being sick), pain in the belly, diarrhoea (loose stools) or constipation, indigestion, wind.

*These side effects have been reported commonly (may affect up to 1 in 10 people)*

- headache.

*These side effects have been reported uncommonly (may affect up to 1 in 100 people)*

- loss of blood in the gastrointestinal tract (causing offensive, tar-coloured stool or blood in vomit), soreness of mouth, belching
- a feeling of fullness or of burning in the upper abdomen (gastritis)
- feeling faint, sweaty or lightheaded
- headache and blurred vision with or without flushing of the face (these may be manifestations of increased blood pressure), flushing
- tiredness, dizziness and pale colour of skin (these may be manifestations of low numbers of red cells in the blood known as anaemia/allergic reactions; swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing; itching; rash)
- sensation of spinning or perception that surrounding objects are moving or spinning (vertigo)
- dizziness, sleepiness
- oedema (swelling) including oedema of the lower limbs.

*These side effects have been reported rarely (may affect up to 1 in 1,000 people)*

- severe diarrhoea with blood and mucous in stool
- onset of asthmatic attacks in patients who have been allergic to NSAIDs or to aspirin at any time in the past
- unusual bleeding or increased tendency to bleed, persistent sore throat and frequent infections (these may occur due to low numbers of blood cells)
- ulcer or bleeding in the stomach or intestine
- 
- palpitations
- burning sensation in the food pipe
- hives (urticaria)
- mood altered, nightmares
- visual disturbances including blurred vision, conjunctivitis (pink eye -an infection of the outer-most layer of the eye that covers the sclera)
- ringing or buzzing in the ear(s).

*These side effects have been reported very rarely (may affect up to 1 in 10,000 people)*

- sudden fever, rigors, sore throat ,and a sharp drop in circulating granular white blood cells (agranulocytosis)

- sudden onset of severe abdominal pain (may be a manifestation of perforation of the bowel wall and is a medical emergency)
- yellowing of skin and whites of eyes with decreased appetite, fatigue, mild fever, muscle or joint aches, nausea and vomiting with abdominal pain (these may be manifestations of liver problems)
- swelling of face, ankles or other parts of the body, with sudden increase or decrease in the amount of urine passed (these may be manifestations of kidney failure)
- dark discolouration of urine, bloody or cloudy urine or any change in your urine output (This may be due to kidney related problems or a condition called interstitial nephritis).

*Not known side effects (frequency cannot be estimated from available data)*

- confusion, disorientation.

There may be changes in the results of certain laboratory tests

- abnormal liver function tests (raised transaminases or bilirubin)
- abnormal kidney function tests (raised creatinine or urea, salt and water retention, increased potassium levels in the blood)
- changes in the blood cell count (leucocytopenia, thrombocytopenia, aganulocytosis).

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

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

## 5. How to Store Meloxicam Ranbaxy tablets

Keep out of the reach and sight of children.

Do not use Meloxicam Ranbaxy 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 Meloxicam Ranbaxy contains

The active substance in Meloxicam Ranbaxy tablets is meloxicam.

Meloxicam Ranbaxy Tablets come in two strengths containing 7.5 mg and 15 mg of meloxicam.

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

## **What Meloxicam Ranbaxy looks like and contents of the pack**

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

PVC/PVdC 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**

*<To be completed nationally>*

### **Manufacturer**

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

### **Representative**

*<To be completed nationally>*

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

Czech Republic-Melobax 15mg tablet  
Denmark- Meloxicam Ranbaxy 7.5/15mgTabletter  
Ireland-Mobicam 7.5/15mg Tablets  
Latvia-Melobax7.5mg tablets/Melobax15mg tablets  
Lithuania-Melobax7.5mg tablets/Melobax15mg tablets  
Poland-Melobax 7.5/15 mg Tablets  
Portugal- Meloxicam Ranbaxy 7.5/15mg Comprimidos  
Slovak-Melobax 15 mg tablet  
Spain-Meloxicam Ranbaxy 15 mg

**This leaflet was last approved in:** December 2011