PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

MELOXICAM 7,5 mg UNIMED tablet

MELOXICAM 15 mg UNIMED tablet

Meloxicam

MELOXICAM UNIMED tablets contain sugar

MELOXICAM 7,5 mg UNIMED: lactose monohydrate 42,86 mg (equivalent to 40,72 mg lactose anhydrous)

MELOXICAM 15 mg UNIMED: lactose monohydrate 85,73 mg (equivalent to 81,44 mg lactose anhydrous).

Read all of this leaflet carefully before you start taking MELOXICAM UNIMED

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MELOXICAM UNIMED has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MELOXICAM UNIMED is and what it is used for

MELOXICAM UNIMED belongs to a group of medicines called non-steroidal anti-inflammatory medicines (NSAIDs) which are used to reduce inflammation and pain in joints and muscles.

MELOXICAM UNIMED is used for the treatment of:

- rheumatoid arthritis (inflammation in the joints)
- painful osteoarthritis (pain and stiffness)
- ankylosing spondylitis (a form of spinal arthritis)
- episodes of acute sciatica (any pain stemming from the irritation of the sciatic/hip nerve).

2. What you need to know before you use MELOXICAM UNIMED

Do not take MELOXICAM UNIMED:

- if you are hypersensitive (allergic) to meloxicam, or to any of the ingredients of MELOXICAM UNIMED (see section 6)
- if you previously suffered from any of the following after taking aspirin or any other pain medication:

- asthma (wheezing, chest tightness, breathlessness)
- skin hives (skin rashes/raised red patches on the skin with severe itching)
- nasal polyps (nasal blockage due to swellings in the lining in your nose)
- angioedema (swelling under the skin)
- if you have experienced heart failure
- if you have or had a stomach ulcer
- if you suffer from severe liver disease
- if you suffer from kidney disease and are not undergoing dialysis
- if you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding)
- if you have a history of bleeding in your stomach or intestines, recent or a history of stomach or bleeding ulcers
- if you have been diagnosed with Crohn's disease or ulcerative colitis (an inflammatory bowel disease with symptoms such as abdominal pain and cramping, rectal pain or bleeding, often bloody diarrhoea)
- if you suffer from any bleeding disorders
- if you have recently undergone heart surgery (for narrowed or blocked arteries)
- if you are a child below the age of 12 years.

Warnings and precautions

Take special care with MELOXICAM UNIMED:

MELOXICAM UNIMED may cause you to have heart and/or blood vessel problems, stomach and/or intestine problems, or skin reactions which may be fatal.

- if you have a history of peptic ulcer (stomach ulcer), in particular with bleeding, you should be cured before starting treatment with MELOXICAM UNIMED.
  Gastrointestinal bleeding or ulcer can occur at any time during treatment, with or without warning symptoms. Tell your doctor if you have ever suffered from oesophagitis (inflammation of the gullet) or gastritis (inflammation of the stomach) or any other gastrointestinal disease e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastroesophageal reflux disease or angiodysplasia (a small malformation of some blood vessels in the gut).
- if you are an elderly patient, you may be more likely to experience the side effects of MELOXICAM UNIMED, especially gastrointestinal disorders, stomach ulcer or perforation (which may be fatal) or bleeding disorders.
- if you have a history of stomach ulcers/ bleeding, your doctor may prescribe the lowest dose of MELOXICAM UNIMED as well an additional medicine to reduce the amount of acid produced in your stomach and to protect the lining of your stomach. Should the symptoms of either stomach ulcer or bleeding occur whilst taking MELOXICAM UNIMED, you should stop taking it immediately.
- if you are receiving heparin or taking warfarin (used to thin your blood), aspirin or any other pain medication (non-steroidal anti-inflammatory medicines - NSAIDs).
- MELOXICAM UNIMED may be associated with an increased risk of heart attack

("myocardial infarction") or stroke. The risk is more likely with prolonged treatment. Do not exceed the recommended duration of treatment.

- if any of the following risk factors apply to you, notify your doctor: high blood pressure, increased cholesterol levels, diabetes and smoking, as these may increase the risk of heart attack or stroke.
- If you have abnormal heart function, high blood pressure or any other conditions that may be worsened by fluid retention (excessive build-up of fluid in the body), notify your doctor.
- If you have heart disease caused by narrowing and/or blocking of blood vessels by cholesterol, stroke, and peripheral arterial disease which is a common circulation problem in which blood flow is reduced to the limbs because of narrowed arteries
- if you notice a skin rash, or any abnormalities of the skin, you should stop taking MELOXICAM UNIMED. Serious skin reactions, which can be fatal, may occur.
- if you suffer from kidney or liver problems or are taking diuretic medicines (water tablets), antihypertensive medicines or if you are dehydrated, your kidney function should be carefully monitored.
- if you have been diagnosed with high levels of potassium in your blood.
- if you are diabetic, your potassium levels should be monitored regularly.
- if you have kidney problems and are taking a medicine called pemetrexed (used in the treatment of cancer), please notify your doctor so that the dose of MELOXICAM UNIMED can be adjusted.
- if you are taking lithium (a mood stabilizer).
- MELOXICAM UNIMED may hide the symptoms of an infection (e.g. fever).
- If you are experiencing difficulty conceiving, you should consider stopping treatment with MELOXICAM UNIMED

- the regular use of MELOXICAM UNIMED in the last three months of pregnancy may cause abnormally high blood pressure in the blood vessels of the baby's lungs which may delay or lengthen labour in the mother.

Other medicines and MELOXICAM UNIMED

Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines.)

This is because the active agent in MELOXICAM UNIMED can affect the way some medicines work. Also, some medicines can affect the way MELOXICAM UNIMED works.

- Aspirin and other anti-inflammatory medication: may increase the risk of stomach ulceration and/or bleeding.
- Medicines which prevent blood clotting or "blood-thinning" medicines, such as warfarin, clopidogrel, ticlopidine or heparin, and medicines which break down blood clots (thrombolytics / anti-platelet medicines), as these may increase the risk of bleeding.
- Selective serotonin re-uptake inhibitors used in the treatment of depression may increase the risk of bleeding.
- Lithium (psychiatric medicine used to treat mood disorders), as MELOXICAM UNIMED 7,5 mg / 15 mg may affect how your medicine works.
- Methotrexate (used in the treatment of tumours, severe skin conditions and active rheumatoid arthritis), as FELOXOCAM may increase the effect of this medicine.
- Medicines used to treat high blood pressure, including diuretics (water tablets), beta-blockers (eg. atenolol), ACE-inhibitors (eg. enalapril), Angiotensin II receptor blockers (eg. losartan) as MELOXICAM UNIMED may reduce the effect of these medicines and your doctor may need to monitor your

kidney function.

- Cholestyramine (used to lower cholesterol levels) may reduce the effect of MELOXICAM UNIMED.
- Ciclosporin or tacrolimus (used after organ transplants or for severe skin conditions, rheumatoid arthritis or nephrotic syndrome) may affect the way your kidneys work.
- Deferasirox (used to treat high levels of iron in the blood) may increase the risk of bleeding and stomach ulcers.
- Pemetrexed (used in the treatment of cancer), as your dose schedule of MELOXICAM UNIMED may need to be adjusted.
- Oral anti-diabetic medicines, such as sulphonealureas and nateglinide.
- Corticosteroids (used to treat various inflammatory or skin conditions) may increase the risk of stomach ulcer and bleeding.

Taking MELOXICAM UNIMED with alcohol

Simultaneous intake of alcohol increases the risk of bleeding.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before using MELOXICAM UNIMED.

Pregnancy:

You should not take MELOXICAM UNIMED during pregnancy. It may harm your unborn baby and interfere with normal labour/delivery.

Breast-feeding

MELOXICAM UNIMED must not be used during breast-feeding.

Fertility

MELOXICAM UNIMED may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

If you feel dizzy or drowsy after taking MELOXICAM UNIMED, do not drive or operate machinery until these effects wear off.

It is not always possible to predict to what extent MELOXICAM UNIMED may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MELOXICAM UNIMED affects them.

Important information about some of the ingredients of MELOXICAM UNIMED:

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

3. How to use MELOXICAM UNIMED

Do not share medicines prescribed for you with any other person.

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

Your doctor will choose the dose that is right for you. Also, the dosing intervals most suitable for you, will be selected by your doctor or health care provider.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- You must take the tablets during or immediately after meals.

The maximum daily dose of MELOXICAM UNIMED is 15 mg.

Adults:

The usual dose is:

Osteoarthritis: 7,5 mg once daily. Increase to 15 mg if necessary.

Rheumatoid arthritis: 15 mg once daily. Reduce dose if possible (provided therapeutic response is maintained).

Ankylosing spondylitis: 15 mg once daily. The dose may be reduced to 7,5 mg/day.

Acute sciatica: 7,5 mg once daily. If there is no improvement the dose can be increased to 15 mg a day.

Your doctor will tell you how long your treatment with MELOXICAM UNIMED will last. If you have the impression that the effect of MELOXICAM UNIMED is too strong or too weak, tell your doctor or pharmacist.

If you take more MELOXICAM UNIMED than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the medicine pack with you. This is so the doctor knows what you have taken.

Symptoms of overdose may include:

- feeling sleepy or tired, nausea, vomiting, stomach pain and bleeding. In severe cases overdose may result in high blood pressure, kidney failure, liver failure, coma, convulsions and heart failure.

If you forget to take MELOXICAM UNIMED

If you forget to take MELOXICAM UNIMED, take as soon as you remember. If it is almost time for your next dose, skip the missed dose and take MELOXICAM UNIMED at the next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking MELOXICAM UNIMED

Do not stop taking this medicine without talking to your doctor first.

4. Possible side effects

MELOXICAM UNIMED can have side effects.

Not all side effects reported for MELOXICAM UNIMED are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using MELOXICAM UNIMED, please consult your health care provider for advice.

If any of the following happens, stop using MELOXICAM UNIMED and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MELOXICAM UNIMED. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- bronchospasm or asthma (cough, difficulty breathing, noisy breathing, shortness of breath, tightness in chest, wheezing)
- the presence of blood in your urine (water)
- chest pain (angina), irregular or rapid heartbeat (palpitations, high blood pressure or low blood pressure), aching sensation in your chest or arms (cardiac arrest)
- cardiac failure (disease of the heart with shortness of breath and swelling of face, feet or lower legs due to fluid build-up)
- the colour of your urine becomes darker, you feel tired, sick and you have no appetite
- swelling in any part of your body
- passing of red, tarry stools as this may be a symptom of a bleeding stomach ulcer
- stroke (sudden numbness in face, arm or leg, especially on one side of the body)
- blistering, peeling or bleeding on any part of your skin with or without a rash (including your lips, eyes, mouth, nose, genitals, hands or feet), flu-like symptoms (fever, chills or aching muscles) which are symptoms of a serious skin reaction (Steven Johnson Syndrome/ toxic epidermal necrolysis (TEN)) which could be fatal
- Skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious skin allergy called ‘erythema multiforme

- Passing less urine than is normal for you
- abnormality of white blood cell or platelet numbers, unusual bleeding or bruising, sore throat, fever and chills
- confusion and disorientation, mood changes, nightmares
- pancreatitis (inflammation of the pancreas) (symptoms may include upper abdominal pain that radiates into the back; swollen and tender abdomen; nausea and vomiting, fever and increased heart rate)
- inflammation of the large bowel (diarrhoea usually with bloody or black-coloured stools and mucous, stomach pain and fever)
- severe, persistent abdominal pain.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- diarrhoea, stomach pain, feeling sick or being sick, indigestion, heartburn
- unusual tiredness or weakness.

Less frequent side effects:

- anaemia (you may feel weak and look pale)
- headache, dizziness, light headedness
- ringing in the ears
- swelling of your lower legs, hands, arms, feet, ankles and legs
- drowsiness
- visual disturbances, blurred vision or other eye problems

- vertigo (feeling unbalanced / spinning head), ringing or buzzing in the ears
- skin rashes or other skin conditions, itching
- flushing
- high blood pressure (headaches, vision problems, blurred vision, irregular heart beat)
- inflammation or soreness of the mouth or gullet, stomach or intestinal ulcer, colitis (inflammation of the colon or Crohn's disease), which may be worsened
- gastrointestinal bleeding, inflammation of the stomach, constipation, flatulence, gastrointestinal perforation (a hole in the all of the GI tract)
- abnormalities in tests of liver function, hepatitis
- sodium and water retention, high potassium levels, abnormal renal function tests, urination problems, renal failure
- ovulation delay

Frequency not known:

- increased sensitivity of the skin to sunlight
- allergic shock with reactions such as difficulty breathing, rash, swelling of the throat, lips or tongue
- confusion
- sleep disturbances, nightmares
- cardiac failure (disease of the heart with shortness of breath and swelling of face, feet or lower legs due to fluid build-up)
- pancreatitis
- infertility in women

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of MELOXICAM UNIMED.

5. How to store MELOXICAM UNIMED

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep blisters in carton until required for use.

Do not use after the expiry date stated on the carton. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MELOXICAM UNIMED contains

The active substance in each MELOXICAM UNIMED 7,5 mg tablet is 7,5 mg meloxicam.

The active substance in each MELOXICAM UNIMED 15 mg tablet is 15 mg meloxicam.

The other ingredients are:

Maize starch, pregelatinized maize starch, colloidal silicon dioxide, sodium citrate, lactose

monohydrate, microcrystalline cellulose, magnesium stearate

What MELOXICAM UNIMED looks like and contents of the pack

MELOXICAM UNIMED 7,5 mg tablets are yellow coloured, 7.0mm, circular, flat, beveled uncoated tablet with central breakline on one side and plain on the other side.

MELOXICAM UNIMED 15 mg tablets are yellow coloured, 10.0mm, circular, flat, beveled uncoated tablet with central breakline on one side and plain on the other side.

BLISTER: Multiple blisters may be packed in a varnished, printed cardboard carton. MELOXICAM UNIMED 7,5 mg and 15 mg tablets are presented in clear, transparent PVC/PVDC and Aluminium foil blister packs.

Holder of Certificate of Registration

Unimed Healthcare (Pty) Ltd

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1827

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Registration number

MELOXICAM 7,5 mg UNIMED: 58/3.1/0236

MELOXICAM 15 mg UNIMED: 58/3.1/0237

Access to the corresponding Professional Information

The Professional Information is contained in the packaging of MELOXICAM UNIMED.