SCHEDULING STATUS

S3

ADCO-MELOXICAM 7,5 (7,5 mg tablets)

Meloxicam

Contains sugar (lactose monohydrate): 114,85 mg

ADCO-MELOXICAM 15 (15 mg tablets)

Meloxicam

Contains sugar (lactose monohydrate): 106,81 mg

Read all of this leaflet carefully you before start taking ADCO-MELOXICAM

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

1. What ADCO-MELOXICAM is and what it is used for

ADCO-MELOXICAM is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain, fever and inflammation.

ADCO-MELOXICAM is indicated for the symptomatic treatment of:

- Rheumatoid arthritis (a chronic inflammatory disorder affecting many joints, including those in the hands and feet)
- Painful osteoarthritis (joint pain in the hands, neck, lower back, knees or hips)
- Ankylosing spondylitis (an inflammatory condition affecting the spine and large joints)
- Episodes of acute sciatica (pain in the hip nerve).

2. What you need to know before you take ADCO-MELOXICAM

Do not take ADCO-MELOXICAM

- if you are hypersensitive (allergic) to meloxicam or any of the other ingredients of ADCO-MELOXICAM (listed in section 6),
- if you think you may have reacted to any other NSAID (e.g. aspirin, ibuprofen) with sensitivity reactions like asthma, acute rhinitis (runny nose), nasal polyps (a painless benign growth on the lining of the nose or sinuses) and urticaria (itchy skin rash),
- if you have heart failure, heart disease, peripheral arterial disease (a circulatory condition in which narrowed blood vessels reduce blood flow to the limbs),
- if you have had a stroke,
- if you have had coronary artery bypass graft (CABG) surgery, since ADCO-MELOXICAM should not be used to treat pain after such an operation,
- if you have active inflammatory bowel disease (Crohn's disease or ulcerative colitis),
- if you have had gastrointestinal (stomach or duodenal) ulcers,
- if you have had bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces) after you have taken other NSAIDs,
- if you have any other bleeding disorders,
- if you have previously had medical problems with your kidney or liver,
- if you are pregnant, do not use NSAIDs at 30 weeks or later in your pregnancy unless specifically advised to do so by your health care professional because these medicines may cause problems in your unborn baby.

Warnings and precautions

ADCO-MELOXICAM may cause heart-related conditions, gastrointestinal conditions, or skin reactions which may be fatal.

Special care should be taken with ADCO-MELOXICAM:

- as higher doses and long duration of treatment can cause heart-related conditions.
- if you have pre-existing heart disease, or possess risk factors for developing heart disease such as high blood pressure high cholesterol, diabetes mellitus and smoking, if you suffer from conditions that cause or can worsen fluid retention.
- if you are elderly, have heart failure or liver or kidney problems, taking diuretics (medicines used to help rid your body of salt (sodium) and water) or certain medicines used to treat high blood pressure, the risk for kidney failure is increased.
- if you are diabetic, blood potassium levels may increase. Your doctor will perform regular monitoring of your blood potassium levels.
- if you are elderly, side effects may happen more often, especially bleeding in the stomach and intestines, ulceration or perforation (which may be fatal).
- if you have had history of gastrointestinal disorders including inflammatory bowel diseases such as hiatus hernia (a condition where part of the stomach moves up into the chest), gastro-oesophageal reflux diseases or angiodysplasia (an abnormality with blood vessels of the gastrointestinal tract).
- if you develop symptoms of bleeding or ulceration during therapy (see section 4), treatment with ADCO-MELOXICAM should be stopped.
- if you develop allergic reactions which cause skin rash, itching, blistering, painful red areas or mucosal lesions (abnormal alteration of the mouth surface), treatment with ADCO-MELOXICAM should be stopped as soon as these symptoms appear.
- if you develop a fever, skin rash, swelling of the lymph nodes and/or swelling of the face (this is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)), stop treatment with ADCO-MELOXICAM and contact your doctor immediately.
- tell your doctor or health care provider if you are pregnant or plan to become pregnant. Taking NSAIDs at around 30 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of your pregnancy, your health care provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs around 30 weeks of pregnancy or later.

ADCO-MELOXICAM may mask the symptoms of an infection.

ADCO-MELOXICAM cannot be taken in place of anticoagulant medicines e.g. aspirin used to prevent blood from clotting.

Children

Do not give ADCO-MELOXICAM to children under the age of 18 as it is unlikely to be safe.

Other medicines and ADCO-MELOXICAM

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

Taking other medicines with ADCO-MELOXICAM:

- anti-inflammatory medicines such as NSAIDs (e.g., aspirin, ibuprofen, etc.) can intensify stomach or bowel side effects,
- anticoagulants (blood thinning tablets like warfarin, heparin) and thrombolytics (medicines used to break down blood clots) may cause enhanced risk of bleeding,
- lithium, as it may cause increase the concentration of lithium in your blood,
- methotrexate may cause serious toxicity,
- angiotensin-converting enzyme (ACE) inhibitors and other antihypertensive medicines (used for the treatment of high blood pressure and heart failure) may have a reduced blood pressure lowering effect,
- the cholesterol lowering medicine colestyramine may lower the effect of ADCO-MELOXICAM,
- ciclosporin and tacrolimus (medicines used after organ transplants) increase the risk of kidney damage,
- diuretics (known as 'water tablets' e.g. furosemide and thiazide) may cause reduced functioning of the kidneys, especially if the patient is dehydrated (see section 2),
- probenecid (used to treat gout) increases the effect of ADCO-MELOXICAM,
- pemetrexed (used to treat certain types of cancer),
- intrauterine device (a device that is implanted in your uterus as a form of contraception), as the concomitant use of NSAID's may cause a reduced efficacy,
- corticosteroids increase the risk of gastrointestinal adverse reactions,
- antidiabetic medicines (e.g. sulphonylureas, nateglinide), may have an increased blood sugar lowering effect,
- selective serotonin reuptake inhibitors (SSRIs) (medicines used in the treatment of depression) and anti-platelet medicines (medicines used to prevent blood clots) increases the risk of gastrointestinal bleeding.

ADCO-MELOXICAM with food and drink

ADCO-MELOXICAM should not be taken with alcohol as this may increase the risk of bleeding.

ADCO-MELOXICAM should be taken with a glass of water and together with a meal (see section 3).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ADCO-MELOXICAM.

The use of ADCO-MELOXICAM in the third trimester of pregnancy may harm unborn child as well as delay and prolong labour.

No data on the influence of fertility is available.

Driving and using machines

ADCO-MELOXICAM may cause dizziness or tiredness, which could have a moderate influence on the ability to perform or execute tasks.

It is not always possible to predict to what extent ADCO-MELOXICAM may interfere with your daily activities. You should ensure that you express caution in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which ADCO-MELOXICAM affects you.

ADCO-MELOXICAM contains lactose

ADCO-MELOXICAM contains lactose and this should be taken into account in patients with diabetes mellitus.

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

3. How to take ADCO-MELOXICAM

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

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

ADCO-MELOXICAM is for oral use only.

The maximum daily dose of ADCO-MELOXICAM is 15 mg for adults.
The tablet should be taken with a glass of water and together with a meal.

For the treatment of:

- *Acute sciatica* (persistent sciatic nerve pain of the lower back): Take 7,5 mg once daily. If there is no improvement the dose can be increased to 15 mg a day.
- *Ankylosing spondylitis* (arthritis that causes pain and stiffness in your spine): Take 15 mg once daily. If there is improvement the dose may be reduced to 7,5 mg per day.
- *Osteoarthritis* (degenerative joint disease): Take 7,5 mg once daily. Increase to 15 mg if necessary.
- *Rheumatoid arthritis* (persistent inflammatory disorder affecting many joints): Take 15 mg once daily. Reduce dose if possible (if the medicine gives you the same results on the lower dose).

Your doctor will tell you how long your treatment with ADCO-MELOXICAM will last.

If you have the impression that the effect of ADCO-MELOXICAM tablets is too strong or too weak, tell your doctor or pharmacist.

If you take more ADCO-MELOXICAM than you should
Overdosage can cause increased severity of side effects (see section 4).

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ADCO-MELOXICAM
Do not take a double dose to make up for forgotten individual dose. Take the dose as soon as you remember.

4. Possible side effects

ADCO-MELOXICAM can have side effects.

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

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

- difficulty in breathing, shortness of breath, coughing or wheezing (signs of bronchospasm),
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing (signs of congestive heart failure),
- hypersensitivity skin reactions (including hives, itching, flushed or pale skin), difficulty breathing, fainting (signs of a life threatening allergic reaction),
- sudden and severe abdominal pain, nausea and vomiting, which can be indicative of perforation (a split in the stomach or intestines) or ulcerative colitis (inflammatory bowel disease),
- fever, skin rash, swelling of the lymph nodes and/or swelling of the face (Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS)),
- allergic reactions which can include flu-like symptoms along with a skin rash, itching, painful red areas, peeling or blistering, swollen face, lips, hands or fingers (Stevens-Johnson's syndrome).

These are all very serious side effects. If you have them, you may have had a serious reaction to ADCO-MELOXICAM. 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:

- changes in the way your heart beats (if you notice it beating faster or slower, skipping a beat),
- heart attack (symptoms include tightness or pain in the chest, neck, back or arms, as well as tiredness, light-headedness, abnormal heartbeat, shortness of breath and anxiety),
- stroke (symptoms include sudden numbness or weakness in the face, arm or leg, confusion or trouble speaking or understanding speech, vision problems, difficulty in walking, loss of balance or problems with coordination),
- gastrointestinal bleeding (symptoms include black or tarry stool, bright red blood in vomit, stomach cramps, dark or bright red blood mixed with stool),

- a whole in the wall of the stomach or intestine (gastrointestinal perforation, symptoms include stomach pain and tenderness, fever, chills, nausea and vomiting),
- inflammation of the liver (hepatitis, symptoms include nausea, vomiting, loss of appetite, generally feeling unwell, fever, yellowing of the skin and eyes, and dark coloured urine),
- kidney problems including kidney failure (swelling of the face, hand and feet, changes in urine colour, passing of little or no urine, nausea, vomiting and tiredness),
- inflammation of the pancreas (symptoms include pain in the abdomen or back, nausea, vomiting, loss of appetite and sweating)

Tell your doctor if you notice any of the following:
Frequent side effects:

- low red blood cell count (anaemia),
- headache, dizziness or light-headedness,
- indigestion or heartburn, nausea, vomiting, diarrhoea, passing of wind, constipation, stomach pain,
- abnormal physical weakness and lack of energy,
- skin rash and itching.

Less frequent side effects:

- abnormal blood cell counts (thrombocytopenia, neutropenia, eosinophilia, leucopoenia, agranulocytosis),
- vertigo (a spinning sensation), confusion, sleeplessness or drowsiness, difficulty falling or staying asleep (insomnia), nightmares,
- blurred vision, inflammation or infection of the eyes (conjunctivitis),
- swelling of the feet or legs,
- high blood pressure,
- stomach or intestinal ulcers, inflammation of the large intestine (symptoms include abdominal pain, diarrhoea and blood in the stool), inflammation of the stomach lining (symptoms include upper stomach pain, nausea and vomiting), painful swelling and sores inside the mouth, burping, inflammation of the oesophagus,
- abnormalities in tests of liver function,
- reddening of the skin (flushing), hives, sensitivity to sun exposure,
- abnormalities in tests for kidney function, increase in potassium levels in the blood,
- tinnitus (ringing or buzzing noise in the ear).

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ADCO-MELOXICAM.

5. How to store ADCO-MELOXICAM

- Store all medicines out of reach of children.
- Store at or below 25 °C in a well-closed container at or below 25 °C.
- Protect from direct sunlight.
- Do not use after the expiry date stated on the label / carton / bottle.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What ADCO-MELOXICAM contains

The active substance is meloxicam.

ADCO-MELOXICAM 7,5: Each tablet contains meloxicam 7,5 mg.

ADCO-MELOXICAM 15: Each tablet contains meloxicam 15 mg.

The other ingredients are colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone cross-linked (crospovidone), povidone, sodium lauryl sulphate and pregelatinised starch.

What ADCO-MELOXICAM looks like and contents of the pack

Yellow, round, flat bevelled edged tablet with break-line on one side.

Contents of the packaging:

10, 30, 100 and 300 tablets

- The tablets are packed in a white opaque polypropylene cylindrical securitainers with a white opaque low density polyethylene (LDPE) to medium density polyethylene (LDPE) snap on lid with and a clean white, circular polyether polyurethane flexible cellular foam insert. A or a white bleached, non-absorbent cotton wool wadding is placed within the securitainer.
- The tablets are packed in a crystal clear, rigid PVC multiple unit blister packs heat-sealed with silver-coloured, plain, hard temper, laminated aluminium foil packed into a cardboard carton.

Not all pack types and pack sizes may be marketed.

Holder of Certificate of Registration

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