1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

LOXIFLAM 7,5 mg tablets

Meloxicam

Contains sugar: Lactose monohydrate 163,5 mg

LOXIFLAM 15 mg tablets

Meloxicam

Contains sugar: Lactose monohydrate 156,0 mg

Read all of this leaflet carefully before you start taking LOXIFLAM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- LOXIFLAM 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 LOXIFLAM is and what it is used for

LOXIFLAM is used in patients aged 12 years and older to relieve symptoms of arthritis such as joint pain and inflammation. It is also used for the symptomatic relief of acute episodes of sciatica (pain in the hip nerve) and ankylosing spondylitis (an inflammatory disease that can cause some of the vertebrae in your spine to fuse together).
Meloxicam belongs to a class of medicines called non-steroidal anti-inflammatories. These medicines are usually used to treat inflammation, swelling, stiffness, pain and fever.

2. What you need to know before you take LOXIFLAM

Do not take LOXIFLAM:

- if you are hypersensitive (allergic) to meloxicam or any of the other ingredients of LOXIFLAM (listed in section 6).
- if you are allergic to aspirin or other anti-inflammatory medicines.
- if you have ever suffered from wheezing, nasal polyps (nasal obstruction due to swellings in the lining of your nose) along with a runny nose, swelling of the skin, urticaria (nettle rash) when taking aspirin or other anti-inflammatory medicines.
- if you have or ever had a recurring gastrointestinal ulcer (ulcer of the stomach or intestines), perforation or bleeding.
- if you have suffered from bleeding in your stomach or intestines, in your brain or throughout your body.
- if you have kidney failure and you are not undergoing dialysis.
- if you have serious liver disease.
- if you have acute asthma.
- if you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding).
- if you suffer from a heart disease caused by inadequate blood or oxygen supply to the heart muscle, if you have had a stroke, or peripheral arterial disease (narrowing

of the arteries that carries the blood away from the heart to other parts of your body).

- if you have active or a history of recurrent ulcer, haemorrhage (loss of circulating blood volume) or perforations (a hole in the wall of the bowel).
- if you have active inflammatory bowel disease (Crohn's disease or ulcerative colitis).
- if you have a history of gastrointestinal bleeding, ulceration or perforation related to the use of previous anti-inflammatory medicines.
- if you are undergoing coronary artery bypass surgery (CABG) do not take LOXIFLAM as an analgesic (pain killer) a day before or a few days after surgery.
- if you have heart failure.
- if you are under the age of 12 years.

Warnings and precautions

Take special care with LOXIFLAM:

- increased risk of heart attack if you experience reactions in the following areas of the body, which may be fatal:
  - the heart and blood vessels,
  - the digestive system (gullet, stomach and intestines) and
  - the skin.
- if you have serious skin reactions, including Drug Rash with Eosinophilia and Systemic Symptoms (DRESS). LOXIFLAM should be discontinued immediately at the first appearance of any type of skin rash, fever, mucosal lesions, or any other sign of hypersensitivity. You should also contact your doctor as soon as possible.
- if you have been prescribed a high dose and prolonged treatment, as this may put you at an increased risk of heart attack (myocardial infarction) or stroke.

- if you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you smoke, have high blood pressure, diabetes, and high cholesterol levels) you should discuss your treatment with your doctor or pharmacist.
- if you take LOXIFLAM, it is not a substitute for aspirin, because it does not have any platelet effects.
- if you develop a skin reaction of any kind, stop taking LOXIFLAM, as some allergic skin reactions have been fatal.
- if you are elderly, as LOXIFLAM can increase the need for high blood pressure medicine.
- if you are elderly, bleeding in the gullet, stomach and intestines can occur at any time during treatment, even if you have no prior history of bleeding in these areas.
- if you are elderly your dosage may need to be reduced.
- if you have hypovolaemia (reduced blood volume) which may occur if you have had serious surgery or low fluid intake, if you have serious blood loss or burns, or if you are taking diuretics (water tablets) or certain medications used to treat high blood pressure.
- Tell your doctor if you are taking anticoagulant medicines (to prevent blood clotting).
- Tell your doctor if you develop any skin rash, sores on the linings of nose, mouth, etc. or other signs of allergy like swollen lymph glands or fever.
- Tell your doctor if you have liver or kidney disease
- if you are experiencing any problems with the functioning of your heart, as this can become worse if you are retaining fluid, a reported side effect of LOXIFLAM.
- if you have an infection since symptoms such as fever and inflammation may be hidden by the effects of LOXIFLAM.

LOXIFLAM may mask the symptoms of an infection.

- if you are frail or debilitated, you may not be able to tolerate the side effects caused by LOXIFLAM tablets.
- as the regular use of LOXIFLAM in the last three months of pregnancy may cause abnormally high blood pressure in the blood vessels of the baby's lungs which makes it harder to pump blood into the lungs, and it may delay or lengthen labour in the mother.
- if gastrointestinal bleeding or ulceration occurs, you should stop taking LOXIFLAM and contact your doctor, treatment should be stopped.
- if you are taking diuretics, discuss taking LOXIFLAM with your doctor as LOXIFLAM may interfere with the effects of diuretics and result in heart and blood pressure problems.
- Tell your doctor if you have ever been diagnosed with high sodium or potassium levels in the blood, or if you are retaining water (swollen hands or feet)
- if you are taking lithium, tell your doctor before you start treatment with LOXIFLAM; if you take these medicines together this can result in toxic levels of lithium in your body.
- if you need to have a thyroid function test, LOXIFLAM may interfere with the test results.
- as LOXIFLAM may reduce the contraceptive effectiveness of the intrauterine device (IUD) (see Other medicines and LOXIFLAM), and you should take additional precautions to avoid falling pregnant.

Children

LOXIFLAM should not be taken by children under the age of 12 years.

Other medicines and LOXIFLAM

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Taking LOXIFLAM together with lithium and methotrexate may result in increased plasma concentrations of these medicines. Therefore, plasma levels of lithium should be monitored when starting or stopping LOXIFLAM, or if doses are adjusted. When taking LOXIFLAM at the same time as methotrexate, strict monitoring of blood cell counts is recommended as the haematological toxicity of methotrexate may be increased.
- Aspirin and other NSAIDs may result in an increase in gastric ulceration and/or bleeding. Concomitant administration is not recommended.
- There may be an increased risk of causing damage to the kidneys if LOXIFLAM is taken together with an ACE-inhibitor, ciclosporin, tacrolimus or a diuretic.
- The blood pressure lowering effect of ACE-inhibitors, beta-blockers, angiotensin receptor blockers (such as irbesartan, losartan, olmesartan) and diuretics may be reduced if taken together with LOXIFLAM. In patients with pre-existing renal impairment this may lead to acute kidney failure.
- If a combination of LOXIFLAM with pemetrexed is necessary, patients should be closely monitored, especially for myelosuppression (a decrease in bone marrow) and gastrointestinal adverse reactions. The administration of LOXIFLAM should be paused for 5 days before, on the day of, and 5 days following pemetrexed administration.
- Convulsions due to an interaction with quinolones may occur.

- The effects of phenytoin and sulphonylurea may be enhanced, therefore there is a risk of worsening of the control of your diabetes or epilepsy. Patients concomitantly taking LOXIFLAM with sulphonylureas or nateglinide should be carefully monitored for hypoglycaemia.
- There is an increased risk of gastrointestinal bleeding and ulceration when LOXIFLAM is taken with alcohol, corticosteroids, bisphosphonates, or oxpentifylline.
- There is an increased risk of bleeding if taken with warfarin, heparin, thrombolytics and ticlopedine. If taking these together cannot be avoided, close monitoring of the anticoagulants is required by your healthcare provider.
- There is a possibility that LOXIFLAM can lead to salt and water retention, particularly when there is an already existing condition of raised blood pressure or kidney impairment.
- The action of diuretics and antihypertensives could be counteracted. The risk of increased potassium levels is more likely to occur if you are also receiving potassium supplements, taking a potassium sparing diuretic or taking an ACE inhibitor (e.g. lisinopril).
- There is inconsistent evidence that concurrent use of low dose aspirin alleviates the increased risk of serious cardiovascular events associated with LOXIFLAM.
- Concomitant use of more than one NSAID (including aspirin) should be avoided because of the increased risk of adverse effects.
- NSAIDs or aspirin should be avoided for 8 to 12 days after mifepristone use, because of the theoretical risk that this may alter the efficacy of mifepristone.
- There have been reports of decreased efficacy of intrauterine devices. Discuss taking LOXIFLAM with your doctor, if you are using an intrauterine contraceptive device, usually known as a coil.

- Adequate hydration is important if diuretics are taken at the same time as LOXIFLAM, and there is the potential to develop renal insufficiency in patients that are dehydrated.
- Cholestyramine may lead to a faster excretion of LOXIFLAM.
- Toxicity of the kidneys may be enhanced with ciclosporin, and during the combined treatment renal function should be assessed regularly.
- The effect of LOXIFLAM may be enhanced by moclobemide, a medicine used for treatment of depression.
- If LOXIFLAM is taken with antiplatelet medicines (to prevent blood clots) and selective serotonin reuptake (SSRIs) inhibitors (antidepressants) there is an increased risk of gastrointestinal bleeding.
- Probenecid (used to manage gout).
- Medicines which break down blood clots (thrombolytics).

LOXIFLAM with food and drink

To reduce the risk of gastrointestinal (gullet, stomach and intestines) effects, LOXIFLAM may be taken with or after food. However, food and milk may reduce the rate and extent of medicine absorption.

Simultaneous intake of alcohol increases the risk of bleeding.

Pregnancy, breastfeeding and fertility

You should not use LOXIFLAM during pregnancy or while breastfeeding.

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 healthcare provider for advice before taking LOXIFLAM.

LOXIFLAM may affect a woman’s ability to fall pregnant as it may delay ovulation.

Driving and using machines

It is not always possible to predict to what extent LOXIFLAM may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which LOXIFLAM affects you (see section 4).

LOXIFLAM contains lactose.

Lactose may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have rare hereditary conditions of lactose or galactose intolerance you should not take LOXIFLAM.

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

3. How to take LOXIFLAM

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

Do not exceed the stated doses.

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

The usual recommended doses are:

Rheumatoid arthritis:

15 mg (one x 15 mg tablet or two x 7,5 mg tablets) once per day. Your doctor may reduce this to 7,5 mg (one x 7,5 mg tablet) once per day, depending on the response.

Painful osteoarthritis:

7,5 mg (one x 7,5 mg tablet) once per day. Your doctor may increase this to 15 mg (one x 15 mg tablet or two x 7,5 mg tablets) once per day, if necessary.

Ankylosing spondylitis:

15 mg (one x 15 mg tablet or two x 7,5 mg tablets) once per day. Your doctor may reduce this to 7,5 mg (one x 7,5 mg tablet) once per day, depending on the response.

Episodes of acute sciatica:

7,5 mg (one x 7,5 mg tablet) once per day. Your doctor may increase this to 15 mg (one x 15 mg tablet or two x 7,5 mg tablets) once per day, if no improvement is seen.

The total daily dosage of LOXIFLAM administered as tablets and injections should not exceed 15 mg. Do not exceed the recommended maximum dose of 15 mg meloxicam per day.

It is important to tell your doctor if you suffer from kidney problems, have a history of gastrointestinal disease or risk factors for heart disease (e.g. high blood pressure, diabetes, high cholesterol or if you are a smoker), as you should receive the lower dose of 7,5 mg LOXIFLAM per day. See Take special care with LOXIFLAM and tell your healthcare provider.

LOXIFLAM should be swallowed with water or other fluid in conjunction with food.
Your doctor will tell you how long your treatment with LOXIFLAM will last. Do not stop treatment early because your symptoms may get worse and you may experience unpleasant side effects.
If you have the impression that the effect of LOXIFLAM is too strong or too weak, tell your doctor or pharmacist.
You should use the lowest effective dose for the shortest possible duration of treatment.

If you take more LOXIFLAM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available,

contact the nearest hospital or poison control centre.

If you forget to take LOXIFLAM

Take your missed dose as soon as you remember, if within a few hours after missing a dose.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

LOXIFLAM can have side effects.

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

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

- Fever,
- swelling around the eyes, lips and face (angioedema), swelling of the hands, feet, ankles, and mouth or throat, which may cause difficulty in swallowing or breathing,
- constriction of air passages (bronchospasm), fainting, shortness of breath,
- severe hypersensitivity allergic reactions such as itching, rashes, urticaria (nettle rash, bullous reactions (severe blistering of the skin or peeling), Stevens-Johnson Syndrome (SJS) (extremely serious allergic skin reaction) and toxic epidermal necrolysis (TEN) (skin degeneration), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS),
- eruption of the skin with lesions (erythema multiforme).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LOXIFLAM. 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:

- Dysrhythmia (tachycardia, congestive cardiac failure, myocardial infarction, cardiovascular thrombotic events, unusual fast or irregular heartbeat or palpitations),
- cardiac failure (disease of the heart with shortness of breath and swelling of the face, feet or lower legs due to fluid build-up),
- ulcers of the stomach or intestines, inflammation or soreness of the mouth or the gullet, inflammation or soreness of the stomach or the colon (colitis),
- relapse of Crohn's disease (inflammation of the last part of the small bowel),
- inflammation of the large bowel (diarrhoea usually with bloody or black-coloured stools (maleana) and mucous, stomach pain and fever),
- vomiting blood or material that looks like coffee grounds,
- severe, persistent abdominal pain,
- abnormality of white-blood cell or platelet numbers (when there is an increase in the production of white blood cells to fight infection or a reaction to a medicine that enhances white cell production), unusual bleeding or bruising, sore throat, fever and chills,
- asthma attacks (seen in people who are allergic to aspirin or other non-steroidal anti-inflammatory medicines),
- blood in the urine (haematuria),
- inflammation of the kidney (nephritis), kidney disease (nephrotic syndrome), kidney failure,
- kidney disease where you pass little or no urine – other symptoms include drowsiness, nausea, vomiting and breathlessness,

- inflammation of the walls of the lung, decrease in the number of eosinophils (white blood cell that fights infection) in the walls of the lung,
- liver disease (with nausea, vomiting, loss of appetite, generally feeling unwell, fever, itching, yellowing of the skin and eyes (jaundice), and dark coloured urine),
- aseptic meningitis (inflammation of the membrane that surrounds the brain and the spinal cord),
- gastrointestinal bleeding, gastrointestinal perforation (a hole in the wall of the bowel),
- internal bleeding in the digestive tract (between the mouth and the stomach) which may not be visible in the stool or vomit,
- vomiting blood (haematemesis).

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:

- Indigestion, feeling sick or being sick, stomach pain, constipation, flatulence (excess amount of gas in the stomach), diarrhoea, stomatitis (inflammation of the mouth), belching, gastritis (inflammation of the stomach),
- light headedness, headache,
- anaemia (reduced red blood cell count),
- swelling caused by fluid retention, including swollen ankles/legs and/or hands,
- mood alterations.

Less frequent side effects:

- Drowsiness (feeling sleepy),
- dizziness or problems with balance (vertigo) and tinnitus (noises in the ear),

- feeling faint, woozy, weak or unsteady (dizzy),
- changes in liver function tests,
- changes in kidney function tests,
- pancreatitis (inflammation of the pancreas that may cause pain that worsens when eating and/or nausea and vomiting),
- micturition disorders (disturbances of the function of urinating),
- delayed ovulation,
- fluid filled blisters (bullous reactions),
- increase in blood pressure, hot flushes.

Side effects with an unknown frequency:

- Confusion and disorientation, insomnia (inability to sleep), nightmares,
- blurred vision, conjunctivitis (inflammation of the white of the eye and the back of the inner surfaces of the eyelids),
- photosensitivity (rashes caused by exposure to sunlight), erythema multiforme (patches of red skin typically on the arms and legs),
- female infertility (not able to get pregnant).

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. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239 -6200

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

5. How to store LOXIFLAM

Store all medicines out of reach of children.

Store at or below 25 °C in well-closed containers.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 LOXIFLAM 7,5 mg contains

The active substance is 7,5 mg meloxicam.

The other ingredients are croscarmellose sodium, lactose monohydrate, povidone K25, sodium stearyl fumarate, trisodium citrate dihydrate.

Contains sugar: Lactose monohydrate 163,5 mg

What LOXIFLAM 15 mg contains

The active substance is 15 mg meloxicam.

The other ingredients are croscarmellose sodium, lactose monohydrate, povidone K25, sodium stearyl fumarate, trisodium citrate dihydrate.

Contains sugar: Lactose monohydrate 156,0 mg

What LOXIFLAM looks like and contents of the pack

LOXIFLAM 7,5 mg is a round, pale yellow, flat bevelled tablet, bisected on one side.

30 tablets are packed in a clear or red polyvinyl chloride, polyvinylidene chloride or a clear polyvinyl chloride, polyethylene, polyvinylidene chloride film sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

LOXIFLAM 15 mg is a round, pale yellow, biconvex tablet.

10 or 30 tablets are packed in a polyvinyl chloride, polyethylene, polyvinylidene chloride or red polyvinyl chloride, polyvinylidene chloride film sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 / +27 11 239 6200

This leaflet was last revised in

04 January 2023

Registration numbers

LOXIFLAM 7,5 mg: 36/3.1/0101

LOXIFLAM 15 mg: 36/3.1/0102

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088/ +27 (0)11 239-6200

Namibia:	NS2
LOXIFLAM 7,5 mg:	05/3.1/0242
LOXIFLAM 15 mg:	05/3.1/0241

ZA_LOXITAB_2301_00