

**PATIENT INFORMATION LEAFLET FOR
COXFLAM 7,5 / 15 TABLETS**

SCHEDULING STATUS: S3

COXFLAM 7,5 (Tablets)

COXFLAM 15 (Tablets)

Meloxicam

Contains sugar:

COXFLAM 7,5: lactose monohydrate 43 mg per tablet.

COXFLAM 15: lactose monohydrate 86 mg per tablet.

Read all of this leaflet carefully before you start taking COXFLAM.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet (see **section 4**).
- COXFLAM 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 COXFLAM is and what it is used for
2. What you need to know before you take COXFLAM
3. How to take COXFLAM
4. Possible side effects

5. How to store COXFLAM
6. Contents of the pack and other information.

1. What COXFLAM is and what it is used for

COXFLAM belongs to a class of medicine known as antirheumatics (anti-inflammatory agents). It is a non-steroidal anti-inflammatory medicine (NSAID) which helps for pain, inflammation and fever.

COXFLAM is used for the symptomatic relief of painful and/or inflammatory conditions, including musculoskeletal and joint disorders such as osteoarthritis, rheumatoid arthritis, acute sciatica (pain in the hip nerve) and ankylosing spondylitis (a form of spinal arthritis).

2. What you need to know before you take COXFLAM

Do not take COXFLAM:

- If you are allergic (hypersensitive) to meloxicam or any of the other ingredients of COXFLAM (listed in **section 6**).
- If you are allergic to aspirin and other anti-inflammatory medicines.
- If you are pregnant (see **Pregnancy, breastfeeding and fertility**).
- If you have ever suffered from wheezing, nasal polyps (nasal obstruction due to swellings in the lining in 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 have ever had a gastrointestinal ulcer (ulcer of the stomach or intestines) or active inflammatory bowel disease (Crohn's disease or ulcerative colitis).
- If you have any kind of bleeding disorder or have ever suffered from gastrointestinal bleeding (bleeding in the stomach) or cerebrovascular bleeding (bleeding in the brain).
- If you have been diagnosed with serious liver disease.
- If you have serious kidney disease and are not undergoing dialysis.
- If you have severe heart failure.

- If you have been diagnosed with ischaemic heart disease (a condition when the blood supply to the heart is reduced due to cholesterol deposits on their walls).
- If you have been diagnosed with peripheral arterial disease (a blood circulation problem due to narrowing of the blood vessels).
- If you are scheduled to undergo coronary artery bypass graft (CABG) surgery and you have pain before the surgery.
- If you are under the age of 12 years.

Warnings and precautions

Take special care with COXFLAM:

- 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, angiodysplasia or hiatus hernia (see **Do not take COXFLAM**).
- If you have high blood pressure.
- If you are elderly.
- If you have heart, liver or kidney disease.
- If you have diabetes.
- If you are a smoker.
- If you have a high blood cholesterol level.
- If you have pre-existing heart failure or high blood pressure since fluid retention have been reported.
- If you have had a recent mild allergic reactions such as urticaria (nettle rash), skin rash caused by aspirin or allergic rhinitis (hay fever).
- If you have hypovolaemia (reduced blood volume) which may occur if you have serious blood loss or burns, surgery or low fluid intake.
- If you are currently using medicines such as diuretics ("water tablets"), or other medicines to treat high blood pressure (known as sartans, angiotensin-II receptor

antagonists or ACE-inhibitors), since COXFLAM combined with these medicines can cause you to be at risk of kidney disease (overt renal decompensation).

- If you have an infection, since COXFLAM may mask symptoms like fever and inflammation.
- If you have ever been diagnosed with high potassium levels in the blood. Your doctor may monitor your progress whilst on treatment.
- Risk of renal impairment and low potassium levels are associated with non-steroidal anti-inflammatory medicine (NSAID) usage.

Other medicines and COXFLAM

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

Please tell your doctor or pharmacist if you are taking, have taken or will be taking any of the following medicines:

- Other anti-inflammatory medicine, including aspirin.
- Medicine which prevent blood clotting for example warfarin.
- Medicines which break down blood clots (thrombolytics).
- Medicines to treat high blood pressure.
- Corticosteroids.
- Ciclosporin [a medicine often used after organ transplants, or for severe skin conditions, rheumatoid arthritis or nephrotic (kidney) syndrome].
- Any diuretic medicine (water tablets). Your doctor may monitor your kidney function if you are taking diuretics.
- Lithium (a medicine used to treat mood disorders).
- Potassium supplements.
- Selective serotonin re-uptake inhibitors used in the treatment of depression.

- Methotrexate (a medicine mainly used to treat tumours or severe uncontrolled skin conditions and active rheumatoid arthritis).
- Cholestyramine (mainly used to lower high blood cholesterol level).
- An intra-uterine contraceptive device (IUD), usually known as a coil. If in doubt ask your doctor or pharmacist.
- Alcohol, see "**COXFLAM with food, drink and alcohol**".

COXFLAM with food, drink and alcohol

COXFLAM should be swallowed with a full glass of water after a meal

COXFLAM should NOT be consumed with alcohol due to the risk of bleeding with simultaneous intake.

Pregnancy, breastfeeding and fertility

Do not take COXFLAM while you are pregnant (see **Do not take COXFLAM**).

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 professional for advice before taking COXFLAM.

It is not known whether COXFLAM passes into breast milk, however other medicines in the same class as COXFLAM are known to pass into breast milk. Therefore, the use of COXFLAM during breastfeeding is not advised.

COXFLAM may reduce female fertility and is not recommended in women attempting to conceive. Women who have difficulties conceiving, or who are undergoing investigation of infertility should not take COXFLAM.

Driving and using machinery:

The effects on ability to drive and use machinery has not been studied with COXFLAM, but should you experience dizziness, drowsiness, visual disturbances or feel light-headed, it would be advisable to refrain from these activities.

It is not always possible to predict to what extent COXFLAM 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 COXFLAM affects them.

COXFLAM contains lactose

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

3. How to take COXFLAM

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

Always take COXFLAM exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

Take the lowest effective dose for the shortest possible duration of treatment.

The usual dose is:

Adults:

Rheumatoid arthritis: 15 mg meloxicam once daily. The dose may be reduced to 7,5 mg daily according to the therapeutic response.

Osteo-arthritis: 7,5 mg meloxicam once daily.

In severe cases: 15 mg meloxicam once daily.

Ankylosing spondylitis: 15 mg once daily.

Acute sciatica: 7,5 mg once daily. The dose may be increased to 15

mg once daily according to the therapeutic response.

Elderly:	7,5 mg meloxicam initially. Careful patient monitoring is recommended.
Dialysis patients:	Do not exceed 7,5 mg meloxicam daily.
Maximum recommended dose:	15 mg meloxicam once daily.
Children under 12 years of age:	Contraindicated (see Do not take COXFLAM).

COXFLAM tablets should be taken with a full glass of water, with or after a meal. Noticeable improvement in severe conditions may require 1 to 2 weeks of continuous use.

Your doctor will tell you how long your treatment with COXFLAM will last.

If you have the impression that the effect of COXFLAM is too strong or too weak, talk to your doctor or pharmacist.

If you take more COXFLAM than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control Centre (see **Warnings and precautions** and **Possible side effects**).

If you forget to take COXFLAM

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

Do not exceed the maximum recommended dose of 15 mg meloxicam daily (one COXFLAM

15 tablet or two COXFLAM 7,5 tablets daily).

4. Possible side effects

COXFLAM can have side effects.

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

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

Those that occur less frequently:

- Allergic reactions which may include a skin rash with blister formation (which may be life-threatening), or purple/red, inflamed spots on your skin.
- Painful, red areas on your skin that spreads quickly, raw areas of skin, discomfort and fever. The skin may peel without blistering and the condition may spread to the eyes, mouth, throat and genitals.

Those that occur with unknown frequency:

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

Those that occur less frequently:

- Severe abdominal pain, chills, fever, nausea and vomiting.
- Gastrointestinal bleeding (abdominal cramps, black or tarry stool, bright red blood in vomit, dark or bright red blood mixed with stool, dizziness or faintness, fatigue, or feeling tired, paleness, shortness of breath, vomit that looks like coffee grounds and

weakness).

- Hepatitis (fatigue, flu-like symptoms, dark urine, pale stool, abdominal pain, loss of appetite, unexplained weight loss, yellow skin and eyes, which may be signs of jaundice).
- Abnormal liver function tests (e.g. raised bilirubin or transaminases).
- Anaemia (shortness of breath, dizziness, headache, coldness in the hands and feet, pale skin and chest pain).
- Bruising of the skin, unusual bleeding, pinpoint red spots on the skin, bleeding from the gums, pale skin, shortness of breath upon exertion, unusual tiredness or weakness, fever and chills, as these symptoms may be due to abnormal blood cell and platelet counts.
- Tinnitus (a ringing, roaring or buzzing sound in the ear).
- Increased blood pressure.
- Urinary disorders (temporarily being unable to pass urine).
- Kidney failure.
- Sodium and water retention.
- High potassium levels in the blood and abnormal kidney function parameters (increased serum creatinine and/or serum urea).
- Inflammatory conditions of the intestine including the lining of the colon (colitis), oesophagus (oesophagitis), stomach lining (gastritis) and mucous membrane of the mouth (stomatitis).
- Eructation (belching).
- Urticaria (a rash of round, red weals on the skin which itch intensely, sometimes with dangerous swelling).
- Pruritus (severe itching of the skin).

Those that occur with unknown frequency:

- Melaena (dark sticky faeces).

- Crohn's disease (diarrhoea, fever and fatigue, abdominal pain and cramping, blood in your stool, reduced appetite and weight loss, anal pain or drainage).
- Peptic ulcers (open sore in the stomach).
- Haematemesis (vomiting blood).
- Cerebrovascular incidents (strokes).
- Peripheral oedema (swelling on the legs and arms).
- Dysrhythmia and tachycardia (irregular and fast heartbeat).
- Heart failure (shortness of breath, difficulty breathing, generalised swelling and tiredness).
- Myocardial infarction (heart attack).
- Increased vulnerability to infection cause by a decreased white blood cell count.
- Photosensitivity reaction.
- Disorientation and confusion.
- Aggravated high blood pressure.
- Risk of renal impairment
- Low potassium levels

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

Tell your doctor if you notice any of the following:

Those that occur frequently:

- Dyspepsia (indigestion).
- Nausea.
- Diarrhoea (loose stools).
- Vomiting.
- Constipation.
- Flatulence (gas).
- Abdominal pain.

- Headache.

Those that occur less frequently:

- Asthma in individuals allergic to aspirin or other non-steroidal anti-inflammatory medicines (NSAIDs).
- Altered mood and nightmares.
- Dizziness and sleepiness.
- Palpitations.
- Flushing.
- Visual disturbances (including blurred vision) and conjunctivitis (inflammation of the eye).
- Allergic reactions.
- Swelling (including swelling of the legs).

Those that occur with unknown frequency:

- Insomnia (inability to sleep).

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 via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of COXFLAM.

5. How to store COXFLAM

Store at or below 30 °C.

Keep the blisters in the outer carton until required for use.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the packaging material.

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 COXFLAM contains

The active substance is meloxicam.

COXFLAM 7,5: Each tablet contains 7,5 mg meloxicam.

Contains sugar (lactose monohydrate 43 mg per tablet).

COXFLAM 15: Each tablet contains 15 mg meloxicam.

Contains sugar (lactose monohydrate 86 mg per tablet).

The other ingredients are **colloidal anhydrous silica, *colloidal silicon dioxide, lactose monohydrate, *low substituted hydroxypropyl cellulose, magnesium stearate, maize starch, microcrystalline cellulose, *povidone, **pregelatinised starch and sodium citrate dihydrate.

*Only present in COXFLAM 7,5.

**Only present in COXFLAM 15.

What COXFLAM looks like and contents of the pack

COXFLAM 7,5: A yellow coloured, circular, flat, bevelled, uncoated tablet, with a central break-line on one side and plain on the other side.

COXFLAM 15: A yellow coloured, circular, flat, bevelled, uncoated tablet, with a central break-line on one side and '15' embossed on the other side.

COXFLAM 7,5: Aluminium foil/amber PVC/PVDC film blister strips of 10 tablets
packed in cartons of 10's, 30's or 100's.

COXFLAM 15: Aluminium foil/amber PVC/PVDC film blister strips of 10 tablets
packed in cartons of 10's, 20's, 30's or 50's.

Holder of certificate of registration

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COXFLAM 7,5: 35/3.1/0055.

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:

The QR Code to be generated
and included after approval.