

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

FLAMARYX 7,5 mg (tablet)

FLAMARYX 15 mg (tablet)

Meloxicam

Contains sugar: Lactose monohydrate

FLAMARYX 7,5 mg: lactose monohydrate 23,50 mg per tablet.

FLAMARYX 15 mg: lactose monohydrate 20, 00 mg per tablet).

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist nurse or healthcare provider.
- **FLAMARYX** 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 **FLAMARYX** is and what it is used for
2. What you need to know before you take **FLAMARYX**
3. How to take **FLAMARYX**
4. Possible side effects
5. How to store **FLAMARYX**
6. Contents of the pack and other information

1. What FLAMARYX is and what it is used for

FLAMARYX contains the active ingredient meloxicam belongs to a group of medications called non-steroidal anti-inflammatory drugs (NSAIDs).

FLAMARYX is used to treat pain or inflammation caused by arthritis. It may be used for osteoarthritis (arthritis caused by a breakdown of the lining of the joints), rheumatoid arthritis (arthritis caused by swelling of the lining of the joints), or ankylosing spondylitis (arthritis that mainly affects the spine).

FLAMARYX is also used to treat sciatica (low back pain combined with pain through the buttock and down one leg).

- **What you need to know before you take FLAMARYX**

Do not take FLAMARYX:

- If you have ever had an unusual or allergic reaction (hypersensitivity) to meloxicam as in **FLAMARYX** or any ingredients of the product.
- If you have ever suffered from asthma, hives, nasal polyps (nasal obstruction due to swellings in the lining in your nose) along with a runny nose, angioedema (painless swelling under your skin) when taking aspirin or other non-steroidal anti-inflammatory medicines.
- If you have recently undergone heart surgery (for narrowed or blocked arteries), since **FLAMARYX** should not be used to treat pain after such an operation.
- If you have or have ever had an ulcer /sore in your stomach or intestines, or perforation or bleeding.
- If you have ever suffered from gastro-intestinal bleeding (bleeding in the stomach or intestines) or holes in the stomach or intestine.
- If you have been diagnosed with Crohn's disease or ulcerative colitis (an inflammatory bowel disease with symptoms such as abdominal pain and cramping, bloody diarrhoea, rectal pain or bleeding, weight loss and fatigue).
- If you have a history of gastrointestinal bleeding or perforation (PUBs) related to previous NSAIDs.
- If you have serious liver disease.
- If you have serious kidney disease and are not undergoing dialysis.
- If you suffer from any kind of established bleeding disorder, bleeding in your stomach or intestines, or recent cerebrovascular bleeding (bleeding in your brain).
- If you have heart failure or ischaemic heart disease (not enough blood flowing to/from your heart).

with symptoms such as shortness of breath, fatigue and swelling in your legs, ankles and feet) and/or a condition that affects the blood vessels and blood supply to your brain (stroke) or peripheral arterial disease (a condition in which narrowed arteries reduce blood flow to your arms or legs).

- If you are pregnant, planning to become pregnant or if you are breastfeeding (see Pregnancy and breastfeeding).
- If you or your child are younger than 12 years of age.
- If you have been told by your doctor that you have an intolerance to some sugars, as

FLAMARYX contains lactose (as monohydrate) (see Important information about some of the ingredients of **FLAMARYX**).

Warnings and precautions

Take special care with FLAMARYX:

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

- The safety and effectiveness of **FLAMARYX** in patients below the age of 12 years has not been determined.
- If you are elderly – older adults have a greater risk of serious side effects on the stomach or intestines, including bleeding or perforation (forming of a hole). These conditions can be fatal.
- The risk of serious side effects on the stomach or intestines, including bleeding or perforation (forming of a hole) is also greater with high doses of **FLAMARYX**, and in patients who have had ulcers.
- If bleeding or ulcers occur while you are taking **FLAMARYX**, you should stop taking **FLAMARYX**.
- If you have ever suffered from any gastrointestinal disease e.g. ulcerative colitis (disease causing inflammation and sores (ulcers) in the lining of the large intestine); Crohn's disease (type of inflammatory bowel disease); hiatus hernia (part of the stomach protrudes through the diaphragm into the chest), gastro-oesophageal reflux disease (backward flow of stomach

contents into the oesophagus), oesophagitis (inflammation of the oesophagus – the swallowing tube that runs from your throat to your stomach) and gastritis (inflammation of the stomach)

- Tell your doctor if you are taking anticoagulant medicines (to prevent blood clotting).
- If you have a history of high blood pressure and/or heart failure.
- If you have liver disease.
- If you have kidney disease
- Your kidney function should be carefully monitored if you have any of the following risk factors:
 - If you are an elderly patient, dehydrated, are taking diuretics (water tablets) or if you have hypovolaemia (reduced blood volume), if you suffer from kidney disease, inflammation of the kidney (lupus nephropathy) or chronic damage to the liver which may occur if you have surgery or low fluid intake.
 - If you develop a skin rash, sores in the lining of your nose or mouth, swollen glands, fever or other signs of an allergic reaction, stop taking **FLAMARYX** and contact your doctor.

Serious skin reactions, some of them fatal, including exfoliative dermatitis (scaling, peeling, and flaking of the skin, and may include itching and hair loss), Stevens-Johnson syndrome, and toxic epidermal necrolysis (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) have been reported.

Drug reaction or rash with eosinophilia and systemic symptoms (DRESS syndrome) with symptoms such as skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cell).

Skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, painful, 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 condition called “erythema multiforme”

- If you have diabetes, high cholesterol or if you are a smoker as these may increase the risk of heart attack or stroke.
- 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)

- You should not take **FLAMARYX** during pregnancy. It may harm your unborn baby and interfere with normal labour/delivery.
- If you are trying to become pregnant. If you have difficulty becoming pregnant or are undergoing investigation to become pregnant, **FLAMARYX** should be stopped
- **FLAMARYX** may mask the symptoms of an infection.

Other medicines with FLAMARYX

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines).

Before taking **FLAMARYX**, tell your doctor if you are using any of the following medicines:

- Aspirin or other non-steroidal anti-inflammatory medicines such as diclofenac, indomethacin, ibuprofen
- Medicines which prevent blood clotting e.g. warfarin and heparin) or thrombolytics (used to thin your blood or break down blood clots).
- Anti-platelet agents e.g. aspirin, clopidogrel, dipyridamole
- Selective serotonin reuptake inhibitors used in the treatment of depression
- Corticosteroids e.g. prednisone (used to treat various inflammatory or skin conditions).
- Lithium (used to treat mood disorders)
- Methotrexate (used to treat cancer, rheumatoid arthritis or inflammation of your joints)
- Angiotensin-converting enzyme (ACE) inhibitors e.g. captopril, enalapril, lisinopril and other medicines used to treat high blood pressure tablets such as diuretics or water tablets
- Cholestyramine – mainly used to lower cholesterol levels.
- Ciclosporin (a medicine often used after organ transplants, or for severe skin conditions, rheumatoid arthritis or nephrotic syndrome)
- Any diuretic medicine (water tablets) – your doctor may monitor your kidney function if you are taking diuretics

- Probenecid (used to treat gout).
- Calcineurin inhibitors or immunosuppressive medicines (used to prevent organ rejection after a transplant), such as ciclosporin or tacrolimus.

If you are using any of these medicines, you may not be able to take **FLAMARYX**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

- Tell your doctor if you are a woman who uses an intrauterine contraceptive device (IUD), usually known as a coil

FLAMARYX with food and drink and alcohol:

- The tablets should be swallowed with water, during a meal.
- Taking this medicine with alcohol may increase the risk of bleeding.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, 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 this medicine.

- Do not take this medicine if you are pregnant or breastfeeding your baby. This medication may be harmful to an unborn baby. Taking **FLAMARYX** during the last 3 months of pregnancy may result in birth defects. Tell your doctor if you are pregnant or plan to become pregnant during treatment.
- The safety of **FLAMARYX** in breastfeeding has not been confirmed. Tell your doctor if you are breast-feeding a baby.
- The use of **FLAMARYX** may impair fertility and is not recommended in women attempting to conceive. **FLAMARYX** may delay ovulation. Therefore, in women who have difficulties conceiving, or who are undergoing investigation of infertility, withdrawal of **FLAMARYX** should be considered.

Driving and using machines:

Drowsiness and blurred vision may occur with this medicine. Do not drive or use machinery until you know how this medication affects you.

It is not always possible to predict to what extent **FLAMARYX** may interfere with your daily activities.

Do not engage in the above activities until you are aware of the measure to which **FLAMARYX** affects you.

FLAMARYX contains lactose monohydrate

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

4. How to take FLAMARYX

- Take this medication only as directed by your doctor.
- Do not take more or less of it or take it more often than prescribed by your doctor
- The tablets should be swallowed with water, during a meal.
- If you need to take two tablets, they must be taken together as one single dose.

The usual recommended doses are given below:

Adults:

- Acute sciatica:
7,5 mg (one tablet) once a day. If there is no improvement, this may be increased to 15 mg once a day.
- Ankylosing spondylitis:
15 mg once a day. Your doctor may reduce your dose to 7,5 mg a day depending on your response to the treatment.
- Osteoarthritis:
7,5 mg (one tablet) once a day. This may be increased to 15 mg once a day.
- Rheumatoid arthritis:
15 mg once a day. This may be reduced to 7,5 mg (one tablet) once a day.

Always take **FLAMARYX** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **FLAMARYX** is too strong or too weak, talk to your doctor or pharmacist.

If you are an elderly patient, have severe kidney disease and are on haemodialysis (treatment to filter wastes and water from your blood), have a history of gastrointestinal disease (a condition affecting your stomach or intestines) or risk factors for heart disease, your doctor may restrict your dose to 7,5 mg a day

If you take more FLAMARYX 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.

Seek emergency medical attention if you think you have used too much of this medicine.

Symptoms of overdose may include lack of energy and enthusiasm, drowsiness, nausea, vomiting, stomach pain or bleeding. In severe cases overdose may result in high blood pressure, kidney failure, liver damage, slow and infective breathing, coma, convulsions (fits) and heart failure.

Allergic reactions may also occur.

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule.

Do not take a double dose to make up for a missed one.

4. Possible side effects

FLAMARYX can have side effects.

Not all side effects reported for **FLAMARYX** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking

FLAMARYX, please consult your health care provider for advice.

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

- swelling of your hands, feet, ankles, face, eyes, lips, tongue, or throat which may cause difficulty in swallowing or breathing or wheezing
- bronchospasm or asthma (tightening of your chest causing difficulty/noisy breathing, shortness of breath or coughing), especially if you are allergic to aspirin or other NSAIDs.
- hives (skin rash) or itching
- fainting
- stroke (sudden numbness/weakness in your face, arm or leg, especially on one side of your body)
- heart attack (chest pain, weakness, shortness of breath).

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

- swelling caused by fluid retention, including swollen ankles/legs black, bloody
- palpitations (rapid irregular action of heart)
- heart failure (a condition where your heart is unable to pump blood around the body properly with symptoms such as shortness of breath, fatigue and swelling in your legs, ankles and feet)
- fever, sore throat, and headache with a severe blistering, peeling and red 342 (these may be signs of a condition known as Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN))
- drug reaction or rash with eosinophilia and systemic symptoms (DRESS syndrome) with symptoms such as skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cell)
- skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, painful, 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 condition called “erythema multiforme”
- jaundice (yellowing of the skin or eyes, dark urine which may be symptoms of liver problems)

such as hepatitis (inflammation of the liver), abnormal liver function tests

- urinating less than usual or not at all (urinary retention), or additional swelling due to fluid retention, nausea, fatigue (kidney damage/failure)
- nephrotic syndrome (swelling around your eyes and in your feet and ankles, foamy urine and weight gain)
- Inflammatory kidney diseases (passing more or less urine than is normal for you, cloudy or bloody urine, dark urine, fever, nausea, vomiting), abnormal kidney functions tests, increased sodium or potassium levels
- stomach or intestinal ulcers/sores, with bleeding and/or perforation, which may be more severe if you are an elderly patient
- causing or worsening of colitis (inflammation of your colon with symptoms such as diarrhoea, black, bloody or tarry stools, coughing up blood or vomit that looks like coffee grounds, stomach pain, loss of appetite and fever)
- inflammation of your stomach (gastritis) (burning ache or pain, nausea, vomiting)
- inflammation of your oesophagus (oesophagitis) (difficulty/painful swallowing, heartburn)
- pale skin, unusual tiredness or weakness.

Frequent side effects:

- shortness of breath, dizziness (anaemia, a condition in which your body does not have enough healthy red blood cells, shortness of breath, dizziness).
- dizziness, headache, light-headedness
- diarrhoea, constipation, abdominal pain, inflammation or soreness of the stomach or colon, indigestion (mild), flatulence (excess amount of air/gas in stomach), feeling sick (nausea), being sick (vomiting)
- skin rash and/or itching

Less frequent side effects:

- unusual bleeding or bruising (abnormal blood test results due to disorders affecting the blood and blood-forming organs, e.g. decreased number of red blood cells, white blood cells or blood platelets which can make your skin pale, cause weakness or breathlessness or make infections more likely)
- drowsiness, confusion, difficulty in falling asleep, nightmares, diarrhoea
- conjunctivitis (redness, pain, swelling of eye or inner lining of eyelid, burning, dry or itching eyes, discharge, excessive tearing), blurred vision
- vertigo (dizziness or spinning sensation), ringing sound in your ears
- increased blood pressure (dizziness, headache)
- flushing (reddening of your face, neck or upper chest)
- inflammation or soreness of the mouth with painful ulcers/sores and swelling (stomatitis)
- constipation, abdominal pain, inflammation or soreness of the stomach or colon, indigestion (mild), flatulence (excess amount of air/gas in stomach), feeling sick (nausea), being sick (vomiting)
- raised, itchy rash (urticaria).
- rashes caused by exposure to sunlight,

Frequency unknown side effects

- Disorientation
- Female infertility (struggling 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 or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **FLAMARYX**.

5. How to store FLAMARYX

Store all medicines out of the reach of children.

Store at or below 25 °C (room temperature). Do not remove tablets from the blister until required for use.

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 FLAMARYX contains

The active substance is meloxicam.

FLAMARYX 7,5 mg: Each uncoated tablet contains 7,5 mg meloxicam.

FLAMARYX 15 mg: Each uncoated tablet contains 15 mg meloxicam.

The other ingredients are cellulose microcrystalline, crospovidone, lactose monohydrate, magnesium stearate, povidone, silica colloidal anhydrous and sodium citrate.

What FLAMARYX looks like and contents of the pack FLAMARYX 7,5 mg:

Light yellow, round, uncoated tablets with score line between 'F' and '1' debossed on one side and plain on the other side.

FLAMARYX 15 mg: Light yellow, round, uncoated tablets with score line between 'F' and '2' debossed on one side and plain on the other side.

Tablets are packed in 250 micron white opaque PVC coated with 60 gsm PVdC and printed aluminium foil with 7 gsm heat seal lacquer. Each blister contains 10 tablets.

Pack size: 30's (3 x 10's)

FLAMARYX 15 mg:

Tablets are packed in 250 micron white opaque PVC coated with 60 gsm PVdC and printed aluminium foil with 7 gsm heat seal lacquer. Each blister contains 10 tablets.

Pack size: 30's (3 x 10's)

Holder of Certificate of Registration

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This leaflet was revised in:

Date of registration:

23 July 2010

Date of revision:

13 August 2025

Registration number

SOUTH AFRICA:

FLAMARYX 7,5 mg: 42/3.1/0469

FLAMARYX 15 mg: 42/3.1/0470

NAMIBIA:

FLAMARYX 7,5 mg: 10/30.1/0078

FLAMARYX 15 mg: 10/30.1/0079