

APPROVED PATIENT INFORMATION LEAFLET

SOUTH AFRICA: S3

FLAMARYX 7.5 mg (tablet)

FLAMARYX 15 mg (tablet)

Meloxicam

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 or your pharmacist.
- **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.

1. 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.

2. WHAT FLAMARYX IS USED FOR

FLAMARYX 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).

3. BEFORE YOU TAKE FLAMARYX

Do not take FLAMARYX:

- If you have ever had an unusual or allergic reaction to meloxicam or any ingredient 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 when taking aspirin or other non-steroidal anti-inflammatory medicines.
- If you have or have ever had a ulcer.
- 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 serious liver disease.
- If you have serious kidney disease and are not undergoing dialysis.
- If you have heart failure.
- If you are pregnant.

Take special care with FLAMARYX:

- The safety and effectiveness of **FLAMARYX** in patients below the age of 18 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) and gastro-oesophageal reflux disease (backward flow of stomach contents into the oesophagus).

- If you develop a skin rash or other signs of an allergic reaction, stop taking **FLAMARYX** and contact your doctor.
- If you have a history of high blood pressure and/or heart failure.
- If you have liver disease.
- If you have kidney disease.
- If you are dehydrated, are taking diuretics (water tablets) or if you have hypovolaemia (reduced blood volume) which may occur if you have surgery or low fluid intake.

Taking FLAMARYX with food and drink:

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

Pregnancy and Breastfeeding:

- Do not take this medicine if you are pregnant. 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.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Driving and using machinery:

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

Taking other medicines with FLAMARYX:

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
- Anti-platelet agents e.g. aspirin, clopidogrel, dipyridamole
- Selective serotonin reuptake inhibitors used in the treatment of depression
- Corticosteroids e.g. prednisone
- Lithium
- Methotrexate
- Angiotensin-converting enzyme (ACE) inhibitors e.g. captopril, enalapril, lisinopril and other medicines used to treat high blood pressure.
- Cholestyramine – mainly used to lower cholesterol levels.
- Ciclosporin
- Any diuretic medicine (water tablets) – your doctor may monitor your kidney function if you are taking diuretics

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

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

(This includes complementary or traditional medicines).

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 (two tablets) once a day.

- Ankylosing spondylitis:
15 mg (two tablets) once a day.
- Osteoarthritis:
7,5 mg (one tablet) once a day. This may be increased to 15 mg (two tablets) once a day.
- Rheumatoid arthritis:
15 mg (two tablets) 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 take more FLAMARYX than you should:

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

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 FLAMARYX:

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.

5. POSSIBLE SIDE EFFECTS

FLAMARYX can have side effects.

Get emergency medical help at once if you have any of these signs of an allergic reaction:

- hives
- difficulty breathing
- swelling of your face, lips, tongue, or throat.

Call your doctor immediately if you have any of these serious side effects:

- black, bloody or tarry stools, coughing up blood or vomit that looks like coffee grounds.

- cloudy or bloody urine
- nausea, stomach pain, loss of appetite, dark urine, clay-coloured stools, jaundice (yellowing of the skin or eyes).
- urinating less than usual or not at all.
- difficult or painful urination
- pale skin, unusual tiredness or weakness
- unusual bleeding or bruising
- fever, sore throat, and headache with a severe blistering, peeling and red skin rash
- skin rash
- itching
- palpitations (rapid irregular action of heart)
- swelling caused by fluid retention, including swollen ankles/legs

Other possible side effects include: dizziness, headache, lightheadedness, drowsiness, confusion, difficulty in falling asleep, nightmares, 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), inflammation or soreness of the mouth, rashes caused by exposure to sunlight, conjunctivitis (redness, pain, swelling of eye or inner lining of eyelid, burning, dry or itching eyes, discharge, excessive tearing), blurred vision, ringing in your ears

Tell your doctor if any of the above side effects are severe, bothersome or do not go away.

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

6. STORING AND DISPOSING OF 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).

7. PRESENTATION OF FLAMARYX

FLAMARYX 7.5 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)

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)

8. IDENTIFICATION OF FLAMARYX

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.

9. REGISTRATION NUMBER/REFERENCE 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

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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