

**PATIENT INFORMATION LEAFLET
FLEXOCAM RANGE**

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:**FLEXOCAM 7,5** (tablets)**FLEXOCAM 15** (tablets)**Read this entire leaflet carefully before you start taking FLEXOCAM.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **FLEXOCAM** 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 FLEXOCAM CONTAINS:

The active ingredient in **FLEXOCAM** is meloxicam.

Each **FLEXOCAM 7,5** tablet contains 7,5 mg meloxicam.

Each **FLEXOCAM 15** tablet contains 15 mg meloxicam.

Inactive ingredients:

Crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, silica colloidal anhydrous, sodium citrate.

FLEXOCAM tablets contain sugar in the form of lactose.

2. WHAT FLEXOCAM IS USED FOR:

Meloxicam belongs to a group of medicines called non-steroidal anti-inflammatory medicines

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(NSAIDs) which are used to reduce inflammation and pain in joints and muscles. **FLEXOCAM** is used for the treatment of:

- Rheumatoid arthritis (inflammation in the joints and resulting in painful deformity and immobility, especially in the fingers, wrists, feet, and ankles)
- Painful osteoarthritis (pain and stiffness, especially in the hip and knee joints)
- Ankylosing spondylitis (a form of spinal arthritis)
- Episodes of acute sciatica (any pain stemming from the irritation of the sciatic nerve)
- Juvenile idiopathic arthritis and other musculoskeletal disorders in children aged 12 to 18 years who are unable to use other anti-inflammatory medicine (the most common type of arthritis in children causing persistent joint pain, swelling and stiffness)

3. BEFORE YOU TAKE FLEXOCAM:

Do not take FLEXOCAM:

- If you are hypersensitive (allergic) to meloxicam, or to any of the other ingredients of **FLEXOCAM** (see “**WHAT FLEXOCAM CONTAINS**”).
- if you have suffered from any of the following after having taken aspirin or any other pain medication: asthma (wheezing, chest tightness, breathlessness), skin hives (skin rashes/raised red patches on the skin with severe itching), nasal polyps (nasal blockage due to swellings in the lining in your nose) or acute rhinitis (runny nose)
- if you have a stomach ulcer
- if you suffer from severe liver disease
- if you suffer from kidney disease and are not undergoing dialysis
- if you are pregnant or breast-feeding your baby
- if you have suffered serious heart failure
- if you have a history of bleeding in your stomach or intestines, recent or a history of stomach or bleeding ulcers
- if you have been diagnosed with a condition called Crohn’s disease or ulcerative colitis (an

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inflammatory bowel disease with symptoms such as abdominal pain and cramping, rectal pain or bleeding, often bloody diarrhoea)

- if you suffer from any bleeding disorders
- if you have recently undergone heart surgery (for narrowed or blocked arteries)
- if you are a child under the age of 12

Take special care with FLEXOCAM:

Do not exceed the dose prescribed by your doctor.

- Avoid taking any other anti-inflammatory medicine with **FLEXOCAM**
- if you require immediate relief from severe or intense pain **FLEXOCAM** is not an appropriate medicine
- if you have a history of oesophagitis (inflammation of the oesophagus with symptoms such as painful swallowing, heartburn, nausea, vomiting), gastritis (inflammation of the lining of the stomach) and/or peptic ulcer (stomach ulcer) or a history of any other disease of the digestive tract, (e.g. Crohn's Disease or Ulcerative Colitis)
- if you are an elderly patient and have a history of gastrointestinal disorders, stomach ulcer or bleeding disorders
- if you have a history of stomach ulcers/ bleeding your doctor will prescribe the lowest dose of **FLEXOCAM** as well an additional medicine to reduce the amount of acid produced in your stomach. Should the symptoms of either stomach ulcer or bleeding occur whilst taking **FLEXOCAM** you should stop taking it immediately
- if you are taking heparin or warfarin (used to thin your blood), aspirin or any other pain medication (non-steroidal anti-inflammatory medicines - NSAIDs) as you should not take **FLEXOCAM**
- if you have a history of hypertension (high blood pressure) or heart disease, taking **FLEXOCAM** may cause water retention which in turn may increase the chances of heart failure

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- if you suffer from have any other heart condition, diabetes or raised cholesterol
- if you develop a serious skin rash that includes dry scaly, itching skin, red or purple spots or blisters
- if you suffer from kidney or liver dysfunction or are taking diuretic agents (water tablets) or are dehydrated, your kidney function should be carefully monitored
- if you are an elderly patient and suffer from congestive heart failure (your heart isn't pumping enough blood to your body), are taking medicine to treat hypertension (high blood pressure) or have reduced blood volume (hypovolaemia) as a result of recent surgery, blood loss, severe burns or low fluid intake
- when taking **FLEXOCAM**, it may hide the symptoms of infection (e.g. fever)
- if you have been diagnosed with high levels of potassium in your blood
- if you have kidney problems and are taking a medicine called pemetrexed (used in the treatment of cancer)
- if you are under the age of 12
- if you have thyroid problems
- if you are pregnant or breastfeeding your baby (**see Do not take FLEXOCAM and Pregnancy and breastfeeding**)

Your doctor may test to monitor your condition before or during your treatment.

Taking FLEXOCAM with food and drink

FLEXOCAM should be administered with food and a glass of water.

Pregnancy and breastfeeding:

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking **FLEXOCAM**.

FLEXOCAM is not recommended for use during pregnancy due to possible harm to the unborn

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baby and interference with normal labour/delivery.

It is unknown if **FLEXOCAM** passes into breast milk. However, as similar medicines pass into breast milk the use of **FLEXOCAM** is not recommended.

Driving and using machines:

FLEXOCAM may cause drowsiness or blurred vision. Do not drive or operate any machinery before you know how this medicine affects you.

Important information about some of the ingredients of FLEXOCAM:

FLEXOCAM contains lactose and should not be taken if you are lactose intolerant or have a rare hereditary problem, or a history of galactose intolerance (a simple sugar found in lactose), Lapp lactose deficiency or glucose–galactose malabsorption.

Taking other medicines with FLEXOCAM:

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

(This includes complementary or traditional medicines.)

Simultaneous use of **FLEXOCAM** with the following medicine can have unwanted interactions.

Please inform your doctor or pharmacist if you are taking or have taken any of the following:

- Aspirin and other anti-inflammatory medication: Co-administration may increase the risk of stomach ulceration and/or bleeding.
- Medicines which prevent blood clotting or “blood-thinning” medicines, such as warfarin, clopidogrel, ticlopidine or heparin, and medicines which break down blood clots (thrombolytics / anti-platelet medicines) as these may increase the risk of bleeding.
- Selective serotonin re-uptake inhibitors used in the treatment of depression may increase the risk of bleeding.
- Lithium (psychiatric medicine used to treat mood disorders) as **FLEXOCAM** may affect how your medicine works.

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- Methotrexate (used in the treatment of tumours, severe skin conditions and active rheumatoid arthritis) as **FELOXOCAM** may increase the effect of this medicine.
- Medicines used to treat high blood pressure, including diuretics (water tablets) as **FLEXOCAM** may reduce the effect of these medicines and your doctor may need to monitor your kidney function.
- Contraception using intrauterine devices (IUD), is decreased when using **FLEXOCAM** and extra methods of contraception should be used.
- Cholestyramine (used to lower cholesterol levels) may reduce the effect of **FLEXOCAM**.
- Cyclosporin or tacrolimus (used after organ transplants or for severe skin conditions, rheumatoid arthritis or nephrotic syndrome) may affect the way your kidneys work.
- Deferasirox (used to treat high levels of iron in the blood) may increase the risk of bleeding and stomach ulcers.
- Pemetrexed (used in the treatment of cancer) as your dose schedule of **FLEXOCAM** may need to be adjusted.
- Alcohol may increase the risk of bleeding.
- Corticosteroids (used to treat various inflammatory or skin conditions) may increase the risk of stomach ulcer and bleeding.

4. HOW TO TAKE FLEXOCAM:

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

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

The maximum daily dose of **FLEXOCAM** is 15 mg.

The usual dose is:

Adults

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Acute sciatica: 7,5 mg once daily. If there is no improvement the dose can be increased to 15 mg a day.

Ankylosing spondylitis: 15 mg once daily

Osteoarthritis: 7,5 mg once daily. Increase to 15 mg if necessary.

Rheumatoid arthritis: 15 mg once daily. Reduce dose if possible (provided therapeutic response is maintained).

Children 12 to 18 years old who are unable to use other anti-inflammatory medicine:

Juvenile idiopathic arthritis and other musculoskeletal disorders:

- less than 50 kg: 7,5 mg once daily
- Over 50 kg: 15 mg once daily

Your doctor will indicate the dosage that is suitable for your condition. The maximum dosage should not be exceeded.

If you take more FLEXOCAM 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.

Symptoms of an overdose may include, feeling sleepy or tired, nausea, vomiting, abdominal pain and bleeding. In severe cases may result in high blood pressure, kidney failure, liver failure coma, convulsions and heart failure.

If you forget to take FLEXOCAM:

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

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5. POSSIBLE SIDE EFFECTS:

FLEXOCAM can have side effects. Not all side effects reported for **FLEXOCAM** are included in this leaflet. Should your general health worsen while taking **FLEXOCAM** please consult your doctor, pharmacist or other health care professional for advice.

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

- Allergic reaction: cough; difficulty swallowing; dizziness; fast heartbeat; hives; itching, puffiness or swelling of the eyelids or around the eyes, face, lips or tongue; shortness of breath; skin rash; tightness in chest; unusual tiredness or weakness; wheezing
- Yellow eyes or skin, also called jaundice

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **FLEXOCAM**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go the casualty department at your nearest hospital if you notice any of the following:

- Bronchospasm or asthma (cough; difficulty breathing; noisy breathing; shortness of breath; tightness in chest; wheezing)
- The presence of blood in your urine (water)
- Increased or fast heart beat (tachycardia).
- Chest pain (angina).
- Irregular heart beat (palpitations, high blood pressure or low blood pressure)
- The colour of your water (urine) becomes darker, you feel tired, sick and you have no appetite
- Swelling in any part of your body
- Passing of red, tarry stools as this may be a symptom of a bleeding stomach ulcer
- Hepatitis with symptoms such as abdominal pain, fatigue, nausea, fever

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Tell your doctor if you notice any of the following:

- You bruise more easily than usual. This could be because of a blood disorder (thrombocytopenia).
- Confusion, drowsiness, sleep disturbances, nightmares, disorientation, mood changes, depression
- abnormal blood test results, anaemia
- abnormal liver function tests
- abnormal urine test results
- passing less or more water (urine) than is normal for you
- peptic ulcer (burning pain in the middle or upper stomach between meals or at night)
- increased or decreased appetite, weight gain or loss
- diarrhoea, constipation, abdominal pain, excess gas (wind),
- Vertigo (feeling unbalanced / spinning head), ringing or buzzing in the ears, hearing loss
- Indigestion, dry mouth, abnormal taste
- nausea, vomiting, fever
- Sensations of tingling, burning, pricking (pins and needles), or numbness
- headache, dizziness, light headedness
- Visual disturbances or other eye problems.
- Flushing, increased sensitivity of the skin to sunlight.
- Skin rashes or other skin conditions, itching
- Mouth ulcers
- unusual tiredness or weakness
- Swelling in any part of the body (oedema)

6. STORING AND DISPOSING OF FLEXOCAM:

- Store at or below 25 °C
- Protect from light

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- Keep the blisters in the carton until required for use
- Do not use after the expiry date printed on the container
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets)
- **KEEP OUT OF REACH OF CHILDREN.**