

PATIENT INFORMATION LEAFLET
FLEXOCAM RANGE

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

FLEXOCAM 7,5 tablets

FLEXOCAM 15 tablets

Read all of this 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 substance in **FLEXOCAM** is meloxicam.

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

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

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

FLEXOCAM 7,5 tablets contain sugar (lactose monohydrate 63 mg per tablet).

FLEXOCAM 15 tablets contain sugar (lactose monohydrate 126 mg per tablet).

2. WHAT FLEXOCAM IS USED FOR:

FLEXOCAM belongs to a group of medicines called non-steroidal anti-inflammatory medicines (NSAIDs) which are used to reduce inflammation and pain in joints and muscles.

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FLEXOCAM is used for the treatment of:

- rheumatoid arthritis (inflammation in the joints)
- painful osteoarthritis (pain and stiffness)
- ankylosing spondylitis (a form of spinal arthritis)
- episodes of acute sciatica (any pain stemming from the irritation of the sciatic/hip nerve).

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 previously suffered from any of the following after taking 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)
 - angioedema (swelling under the skin)
 - acute rhinitis (runny nose).
- if you have experienced heart failure, heart disease caused by narrowing and/or blocking of blood vessels by cholesterol, stroke, and peripheral arterial disease which is a common circulation problem in which blood flow is reduced to the limbs because of narrowed arteries.
- 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 breastfeeding your baby (see **Pregnancy and breastfeeding**).
- if you have a history of bleeding in your stomach or intestines, recent or a history of stomach or bleeding ulcers.

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- if you have been diagnosed with Crohn's disease or ulcerative colitis (an 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 below the age of 18 years.

Take special care with FLEXOCAM:

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

Do not exceed the dose prescribed by your doctor.

- As soon as you notice a skin rash, abnormal area of tissue (wound, sore, rash or boil), you should stop taking **FLEXOCAM**. Serious skin reactions, which can be fatal, may occur.
- If any of the following heart or blood vessel risk factors apply to you, notify your doctor: high blood pressure, increased cholesterol levels, diabetes and smoking. If you have abnormal heart function, high blood pressure or any other conditions that may be worsened by fluid retention (excessive build-up of fluid in the body), notify your doctor. Fluid retention has been observed in patients taking **FLEXOCAM**.
- 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), you should be cured before starting treatment with **FLEXOCAM**.
- If you are an elderly patient, you may be more likely to experience the side effects of **FLEXOCAM**, especially gastrointestinal disorders, stomach ulcer or bleeding disorders.

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- If you have a history of stomach ulcers/ bleeding your doctor may prescribe the lowest dose of **FLEXOCAM** as well as an additional medicine to reduce the amount of acid produced in your stomach and to protect the lining of your stomach. Should the symptoms of either stomach ulcer or bleeding occur whilst taking **FLEXOCAM**, you should stop taking it immediately.
- If you are receiving heparin or taking 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 suffer from kidney or liver problems or are taking diuretic medicines (water tablets) or if you 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 a reduced blood volume (hypovolaemia) as a result of recent surgery, blood loss, severe burns or low fluid intake.
- 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), please notify your doctor so that the dose of **FLEXOCAM** can be adjusted.
- Avoid taking any other anti-inflammatory medicine with **FLEXOCAM** as it may cause an increased risk of bleeding.
- If you require immediate relief from severe or intense pain **FLEXOCAM** is not an appropriate medicine for that.
- When taking **FLEXOCAM**, it may hide the symptoms of infection (e.g. fever).
- If you are diabetic, your potassium levels should be monitored regularly.
- If you have thyroid problems.
- If you have asthma.

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- If you are pregnant or breastfeeding your baby (see **Do not take FLEXOCAM, and Pregnancy and Breastfeeding**).
- If you have an intra-uterine device (IUD), as **FLEXOCAM** may reduce its contraceptive effectiveness.

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

If you do not notice any improvement in your health after several days, please notify your doctor.

Taking FLEXOCAM with food and drink:

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

Alcohol may increase your risk of bleeding, if taken with **FLEXOCAM**.

Pregnancy and breastfeeding:

You should not take **FLEXOCAM** during pregnancy. It may harm your unborn baby and interfere with normal labour/delivery.

FLEXOCAM may pass into breast milk, as similar medicines also pass into breast milk. If you are taking **FLEXOCAM** you should not be breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **FLEXOCAM**.

FLEXOCAM is not recommended in woman who are trying to fall pregnant, woman who are having difficulty falling pregnant or woman who are undergoing testing since it may affect female fertility.

Driving and using machinery:

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

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Important information about some of the ingredients of FLEXOCAM:

FLEXOCAM contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **FLEXOCAM**.

FLEXOCAM contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with FLEXOCAM:

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

(This includes complementary or traditional medicines.)

Taking **FLEXOCAM** with any of the following medicines 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: 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.
- Methotrexate (used in the treatment of tumours, severe skin conditions and active rheumatoid arthritis) as **FLEXOCAM** 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.
- Cholestyramine (used to lower cholesterol levels) may reduce the effect of **FLEXOCAM**.

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- Ciclosporin 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.
- Corticosteroids (used to treat various inflammatory or skin conditions) may increase the risk of stomach ulcer and bleeding.
- Contraception using intrauterine devices (IUDs), is decreased when using **FLEXOCAM** and extra methods of contraception should be used.

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 or pharmacist if you are unsure. If you have the impression that the effect of **FLEXOCAM** is too strong or too weak for you, talk to your doctor or pharmacist.

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

The usual dose is:

Adults

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).

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Your doctor will indicate the dosage that is suitable for your condition. You should not take more than the maximum dosage.

If you take more FLEXOCAM 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.

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

If you forget to take a dose of 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 **FLEXOCAM** at the next regularly scheduled time. Do not take a double dose to make up for a forgotten individual dose.

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 or if you experience any untoward effects while taking **FLEXOCAM**, please consult your doctor, pharmacist or other healthcare 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.

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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 or rapid heartbeat (palpitations, high blood pressure or low blood pressure), aching sensation in your chest or arms
- 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
- stroke (sudden numbness in face, arm or leg, especially on one side of the body).

Tell your doctor if you notice any of the following:

Frequent side effects:

- anaemia (you may feel weak and look pale)
- diarrhoea, constipation, stomach pain, excess gas (wind), feeling sick or being sick, indigestion, heartburn
- hearing loss
- headache, dizziness, light headedness
- skin rashes or other skin conditions, itching
- unusual tiredness or weakness.

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Less frequent side effects:

- you bruise more easily than usual. This could be because of a blood disorder (thrombocytopenia)
- drowsiness, sleep disturbances, nightmares, mood changes
- abnormal blood test results
- abnormal liver function tests
- abnormal urine test results
- yellow eyes or skin, also called jaundice
- passing less or more water (urine) than is normal for you
- increased or decreased appetite, weight gain or loss
- vertigo (feeling unbalanced / spinning head), ringing or buzzing in the ears
- aseptic meningitis (symptoms include a fever, chills, a stomach ache, a painful headache, body aches, loss of appetite and vomiting)
- dry mouth, abnormal taste
- sensations of tingling, burning, pricking (pins and needles), or numbness
- visual disturbances, blurred vision or other eye problems.
- flushing, increased sensitivity of the skin to sunlight, sweating
- high blood pressure, low blood pressure (headaches, vision problems, blurred vision, irregular heartbeat)
- stomach problems (symptoms include blood in stool and/or vomit, bloating, heartburn).

Side effects with frequency unknown:

- confusion, disorientation, depression
- peptic ulcer (burning pain in the middle or upper stomach between meals or at night).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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6. STORING AND DISPOSING OF FLEXOCAM:

- Store at or below 25 °C.
- Protect from light.
- Keep the blisters in the carton until required for use.
- Store all medicines out of reach of children.
- 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).