

PATIENT INFORMATION LEAFLET
FLEXOCAM RANGE

SCHEDULING STATUS

S3

FLEXOCAM 7,5 mg tablet

FLEXOCAM 15 mg tablet

Meloxicam

FLEXOCAM tablets contain sugar (FLEXOCAM 7,5 mg contains 63,0 mg lactose monohydrate per tablet and FLEXOCAM 15 mg contains 126,0 mg lactose monohydrate per tablet).

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, pharmacist, nurse or other health care provider.
- 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.

What is in this leaflet

1. What FLEXOCAM is and what it is used for
2. What you need to know before you use FLEXOCAM
3. How to use FLEXOCAM
4. Possible side effects
5. How to store FLEXOCAM
6. Contents of the pack and other information

1. What FLEXOCAM is and what it is used for

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FLEXOCAM belongs to a group of medicines called nonsteroidal anti-inflammatory medicines (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)
- 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).

2. What you need to know before you use FLEXOCAM

Do not take FLEXOCAM:

- if you are hypersensitive (allergic) to meloxicam, or to any of the ingredients of FLEXOCAM (see section 6)
- 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

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- 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
- 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.

Warnings and precautions

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.

- 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 perforation (which may be fatal) or bleeding disorders.
- if you have a history of stomach ulcers/ bleeding, your doctor may prescribe the lowest dose of FLEXOCAM as well 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

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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 (nonsteroidal anti-inflammatory medicines - NSAIDs), as you should not take FLEXOCAM.
- 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.
- 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.
- FLEXOCAM may be associated with an increased risk of heart attack (“myocardial infarction”) or stroke. The risk is more likely with prolonged treatment. Do not exceed the recommended dose or duration of treatment.
- 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, as these may increase the risk of heart attack or stroke.

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 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 taking FLEXOCAM for longer than the recommended time or at higher than recommended doses you are at risk of serious harm. These include serious harm to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).
- if you are an elderly patient and suffer from congestive heart failure (your heart isn't

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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.
- when taking FLEXOCAM, it may hide the symptoms of infection (e.g. fever).
- the regular use of FLEXOCAM in the last three months of pregnancy may cause abnormally high blood pressure in the blood vessels of the baby's lungs which makes it harder to pump blood into the lungs, and it may delay or lengthen labour in the mother.
- if you are taking lithium (a mood stabilizer).
- if you are diabetic, your potassium levels should be monitored regularly.
- if you have thyroid problems.
- if you are under the age of 18.
- if you have asthma.

Other medicines and FLEXOCAM

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

- 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.

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- 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.
- contraception using intra-uterine devices (IUDs) is decreased when using FLEXOCAM and extra methods of contraception should be used.
- 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.
- probenecid (used to manage gout) may increase the effects of FLEXOCAM.
- cholestyramine (used to lower cholesterol levels) may reduce the effect of FLEXOCAM.
- 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.
- oral anti-diabetic medicines, such as sulphonylureas and nateglinide
- corticosteroids (used to treat various inflammatory or skin conditions) may increase the risk of stomach ulcers and bleeding.

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.

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Pregnancy, breastfeeding and fertility

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

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.

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 or delay ovulation.

Driving and using machines

FLEXOCAM may cause drowsiness or blurred vision.

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

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.

3. How to use FLEXOCAM

Do not share medicines prescribed for you with any other person. Always use FLEXOCAM exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

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The maximum daily dose of FLEXOCAM is 15 mg.

Adults:

The usual dose is:

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).

Your doctor will tell you how long your treatment with FLEXOCAM will last. If you have the impression that the effect of FLEXOCAM is too strong or too weak, tell your doctor or pharmacist.

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 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 FLEXOCAM

If you forget to take FLEXOCAM, take 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 forgotten individual doses.

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If you stop taking FLEXOCAM

Do not stop taking this medicine without talking to your doctor first.

4. 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 using FLEXOCAM, please consult your health care provider for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

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 to 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
- cardiac failure (disease of the heart with shortness of breath and swelling of face, feet or lower legs due to fluid build-up)

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- the colour of your 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, yellow eyes or skin, also called jaundice
- stroke (sudden numbness in face, arm or leg, especially on one side of the body)
- 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) which are symptoms of a serious skin reaction (Stevens- Johnson Syndrome/ toxic epidermal necrolysis (TEN)) which could be fatal
- Skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, 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 allergy called 'erythema multiforme'
- passing less urine than is normal for you
- abnormality of white blood cell or platelet numbers, unusual bleeding or bruising, sore throat, fever and chills
- confusion and disorientation, mood changes, depression
- pancreatitis (inflammation of the pancreas) (symptoms may include upper abdominal pain that radiates into the back; swollen and tender abdomen; nausea and vomiting, fever and increased heart rate)
- inflammation of the large bowel (diarrhoea usually with bloody or black-coloured stools and mucous, stomach pain and fever)
- severe, persistent abdominal pain.

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

Tell your doctor if you notice any of the following:

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Frequent side effects:

- anaemia (you may feel weak and look pale)
- headache, dizziness, light headedness
- hearing loss
- swelling of your lower legs, hands, arms, feet, ankles and legs
- diarrhoea, constipation, stomach pain, feeling sick or being sick, indigestion, heartburn
- skin rashes or other skin conditions, itching
- unusual tiredness or weakness.

Less frequent side effects:

- abnormal blood test results
- increased or decreased appetite, weight gain or loss
- drowsiness, sleep disturbances, nightmares
- aseptic meningitis (symptoms include a fever, chills, a stomach ache, a painful headache, body aches, loss of appetite and vomiting)
- visual disturbances, blurred vision or other eye problems
- vertigo (feeling unbalanced / spinning head), ringing or buzzing in the ears
- flushing, increased sensitivity of the skin to sunlight, sweating
- high blood pressure, low blood pressure (headaches, vision problems, blurred vision, irregular heart beat)
- dry mouth, abnormal taste, soreness of the gullet, heartburn, excess gas (wind)
- inflammation or soreness of the mouth or gullet, stomach or intestinal ulcer, colitis (inflammation of the colon or Crohn's disease), which may be worsened
- abnormalities in tests of liver function
- passing less or more water (urine) than is normal for you, abnormal kidney function test results

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- delayed ovulation
- sensations of tingling, burning, pricking (pins and needles), or numbness.

The following side effects have been reported but the frequency for them to occur is not known:

- peptic ulcer (burning pain in the middle or upper stomach between meals or at night)
- female infertility.
- FLEXOCAM, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link:

<https://www.sahpra.org.za/Publications/Index/8> or

<http://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/>. By reporting side effects, you can help provide more information on the safety of FLEXOCAM. You can also send an email directly to the company., pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store FLEXOCAM

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Store all medicines out of reach of children.

Store at or below 25 °C

Protect from light.

Keep blisters in carton until required for use.

Do not use after the expiry date stated on the carton.

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 FLEXOCAM contains

The active substance in each FLEXOCAM 7,5 tablet is 7,5 mg meloxicam.

The active substance in each FLEXOCAM 15 tablet is 15 mg meloxicam.

The other ingredients are:

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

What FLEXOCAM looks like and contents of the pack

FLEXOCAM 7,5 tablets are light yellow, round biconvex, bevelled-edged with B and 18 debossed on one side and plain on the reverse.

FLEXOCAM 15 tablets are light yellow, round biconvex, bevelled-edged with B and 19 debossed on either side of breakline on one side and plain on the reverse.

FLEXOCAM 7,5 tablets are packed into hard temper aluminium, white, opaque PVC/PVdC blister packs of 30 tablets in an outer carton.

FLEXOCAM 15 tablets are packed into hard temper aluminium, white, opaque PVC/PVdC blister packs of 10 tablets in an outer carton.

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Not all pack sizes are marketed

Holder of Certificate of Registration

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NAMIBIA:

FLEXOCAM 7,5: NS2 06/3.1/0205

FLEXOCAM 15: NS2 06/3.1/0204

BOTSWANA:

FLEXOCAM 7,5: NS2 BOTO1101978

FLEXOCAM 15: NS2 BOT1101977A

FLEXOCAM 15: NS2 BOT1101977B