

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. Keep this leaflet. You may need to read it again. If you have more questions, ask your doctor or pharmacist. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

MELCAM tablets 7.5 mg

MELCAM tablets 15 mg

Meloxicam

What is in this leaflet:

1. What **MELCAM** is and what it is used for
2. Before you take **MELCAM**
3. How to take **MELCAM**
4. Possible Side Effects
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1. What MELCAM is and what it is used for

MELCAM tablets belong to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs) which can be used to reduce inflammation and pain in joints and muscles.

MELCAM tablets are used for:

- the short-term treatment of the symptoms of acute attacks of osteoarthritis;
- the long-term treatment of the symptoms of:
 - rheumatoid arthritis,
 - ankylosing spondylitis (a disease of the backbone).

2. Before you take MELCAM

Do not take **MELCAM** tablets and tell your doctor if you:

- are allergic to **MELCAM** or to any of the other ingredients (See section 6 for a list of these);
- are pregnant, planning to become pregnant or if you are breastfeeding;
- are allergic to aspirin or to other non-steroidal anti-inflammatory medicines (NSAIDs);
- have ever developed signs of asthma (wheezing), nasal polyps along with a runny nose, swelling of the skin or nettle-rash, when taking aspirin or other anti-inflammatory medicines;
- have or have ever had an ulcer of the stomach or intestines;
- have any kind of bleeding disorder or have ever suffered from bleeding in the stomach or intestines or bleeding in the brain;
- have severe liver disease;
- have severe kidney failure and are not receiving dialysis;
- suffer from severe heart failure
- have Crohn's disease
- have ulcerative colitis
- suffer from pain after coronary artery bypass

If you think any of these apply to you, do not start taking these **MELCAM** tablets.

Talk to your doctor first and follow the advice given to you.

Take special care with **MELCAM**

Tell your doctor or pharmacist before taking this medicine:

- if you have high blood pressure;
- if you have heart, liver or kidney disease;
- if you have diabetes;
- if you are elderly (65 years old or more);
- if you have ever been diagnosed with high potassium levels in the blood;

Tell your doctor if you think any of these apply to you.

Warning

Medicines such as these **MELCAM** tablets may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

Discuss your treatment with your doctor or pharmacist if you have heart problems, have previously had a stroke or you think you might be at risk of conditions such as high blood pressure, diabetes or high cholesterol, or if you are a smoker.

Taking other medicines

When you are taking **MELCAM** tablets, do not take any other medicines – including medicines obtained without a prescription – without first talking to your doctor or pharmacist. Tell your doctor or pharmacist if you are taking any of the following medicines:

- any other non-steroidal anti-inflammatory drugs (NSAIDs),
- including aspirin;
- medicines to prevent blood clotting, such as warfarin;
- medicines to break down blood clots;
- medicines to treat high blood pressure;
- oral corticosteroids;
- cyclosporin;
- any diuretic medicine (your doctor may monitor your kidney function if you are taking diuretics);
- lithium, used to treat mood disorders;

- selective serotonin re-uptake inhibitors, used in the treatment
- of depression;
- methotrexate;
- colestyramine;
- you use an intrauterine contraceptive device (IUD), usually known as a coil.

Pregnancy and breast-feeding

MELCAM tablets are not recommended for use by women who are pregnant or breast-feeding.

Tell your doctor immediately if you are pregnant, think you may be pregnant, or if you are breast-feeding. Ask your doctor or pharmacist for advice before using any medicine.

Children (under 16 years old)

This medicine must not be given to children under 16 years old.

Driving and using machinery

Do not drive or operate machinery until you know how **MELCAM** tablets affect you.

If the tablets make you feel light-headed, dizzy or drowsy, or cause blurred vision, do not drive or operate machinery.

Important information about some of the ingredients of **MELCAM** tablets

MELCAM contain lactose

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

3. HOW TO TAKE MELCAM TABLETS

Always take **MELCAM** tablets exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure. Read the label carefully.

Dosage

The dose depends on the medical condition which is being treated. Your doctor will let you know how much you should take. For the treatment of acute attacks of osteoarthritis:

The usual dose is 7.5 mg (one tablet) a day. Your doctor may increase your dose to 15 mg (two tablets) a day, if necessary. For the treatment of rheumatoid arthritis and ankylosing spondylitis:

The usual dose is 15 mg (two tablets) a day. Your doctor may reduce your dose to 7.5 mg (one tablet) a day if necessary.

If you are aged 65 years and over, the recommended dose for the long term treatment of rheumatoid arthritis and ankylosing spondylitis is 7.5 mg (one tablet) a day.

If you have any of the conditions listed in Section 2 under the heading "Take special care with **MELCAM** tablets", your doctor may restrict your dose to 7.5 mg (one tablet) a day.

If you feel that the effect of these **MELCAM** tablets is too strong or too weak, or after several days you do not feel any improvement in your condition, consult your doctor or pharmacist.

If you take more of this medicine than you should Contact your doctor or pharmacist immediately or go immediately to the accident and emergency department of your nearest hospital, taking this leaflet or the tablets with you.

If you forget to take your tablet

Never take two doses on the same day to make up for one you have missed. Take your usual dose the next day.

4. Possible Side Effects

Like all medicines, **MELCAM** tablets can cause side effects, although not everybody gets them.

-If you have a history of gastrointestinal symptoms while taking anti inflammatory drugs, your doctor may monitor your progress while you are having this treatment.

Clinical trials and scientific data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of blood clots in the arteries (which could, for example, lead to heart attack or stroke). Contact your doctor immediately, or go immediately to the accident and emergency department of your nearest hospital, (taking this leaflet or the tablets with you), if you get the following serious side effects:

- severe allergic reactions which may include fainting, shortness of breath, skin reactions and asthma attacks (common side effect: affects 1 to 10 users in 100);
- bleeding in the stomach or intestines, peptic ulcers, soreness or inflammation of the mouth, or inflammation of the gullet (uncommon side effect: affects 1 to 10 users in 1,000);
- severe blistering or peeling of the skin, swelling around the eyes,

lips and face, rashes caused by exposure to sunlight (rare side effect: affects 1 to 10 users in 10,000).

Contact your doctor if you get the following side effects:

Pancreatitis (inflammation of the pancreas)

Common side effects (affects 1 to 10 users in 100):

- indigestion, feeling or being sick, abdominal pain, constipation, flatulence, diarrhoea; skin rashes or itching;
- light-headedness, headaches;
- swelling of ankles and legs;
- anaemia.

Uncommon side effects (affects 1 to 10 users in 1,000):

- hypersensitivity;
- nettle rash or hives;
- dizziness, tinnitus, drowsiness;
- irregular heart beat, increased blood pressure, hot flushes;
- abnormal white blood cell or platelet numbers;
- changes to liver function;
- salt and water retention, excessive potassium, changes to kidney function.

Rare side effects (affects 1 to 10 users in 10,000):

- a hole in the bowel wall, inflammation or soreness of the stomach or intestines (ulcers of the stomach or intestines, bleeding and perforations in the stomach or intestines can occur at any time, can some times, especially in the elderly, be severe and could, very rarely, in fewer than 1 in every 10,000 patients treated, be fatal);
- confusion, mood swings, insomnia, nightmares;
- visual disturbances such as blurred vision;
- inflammation of the liver (hepatitis);
- kidney failure.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Melcam

Keep out of the reach and sight of children. Do not store above 25 C. Do not use **MELCAM** tablets after the expiry date, which is stated on the pack. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What MELCAM tablets contain

Each **MELCAM** 7.5 mg tablet contains 7.5 mg **MELCAM**.
Each **MELCAM** 15 mg tablet contains 15 mg **MELCAM**.
The other ingredients are: lactose monohydrate, microcrystalline cellulose, copovidone, crospovidone, sodium citrate, silicon colloidal anhydrous, magnesium stearate

What MELCAM tablets look like and contents of the pack

Box of 30 (3 x 10) tablets, (uniform, light yellow, round, flat tablets with brake line on one side) of 7,5 mg meloxicam in blister pack.
Box of 30 (3 x 10) tablets, (uniform, light yellow, round, flat tablets with brake line on one side) of 5 mg meloxicam in blister pack.

Manufacturer and Marketing Authorisation Holder

ZADA Pharmaceuticals Ltd.
Donji Bistarac without number
75 300 Lukavac
Bosnia and Herzegovina

Date and number of renewal of marketing authorization

Melcam , tablet, 30 x 7,5 mg:	
Number: 04-07.3-2-2812/16	Date: 21.03.2017.
Melcam , tablet, 30 x 15 mg:	
Number: 04-07.3-2-2813/16	Date: 21.03.2017.