MELOCAM TABLET

Meloxicam (7.5mg)

What is in this leaflet

- 1. What MELOCAM TABLET is used for
- 2. How MELOCAM TABLET works
- 3. Before you use MELOCAM TABLET
- 4. How to use MELOCAM TABLET
- 5. While you are using MELOCAM TABLET
- 6. Side effects
- 7. Storage and disposal of MELOCAM TABLET
- 8. Product description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision

What MELOCAM TABLET is used for

MELOCAM TABLET is used for relief of pain and inflammation in rheumatic disease; exacerbation of osteoarthritis (arthrosis, degenerative joint disease) and ankylosing spondylitis (chronic inflammatory diseases of the skeleton).

How MELOCAM TABLET works

Meloxicam is in a class of medications called NSAIDs. It works by stopping the body's production of a substance that causes pain, fever, and inflammation.

Before you use MELOCAM TABLET

-When you must not use it

Do not use MELOCAM TABLET:

- if you have had asthma, angioedema (swelling of your skin), urticarial (itching or hives), nasal polyps and the symptoms become worsen caused by Aspirin or NSAIDs.
- if you have active stomach ulceration.
- if you have severe liver or kidney problem.
- if you are hypersensitivity to NSAIDs.
- if you are under 15 years old.
- if you are pregnant or breastfeeding.

-Before you start to use it

Please consult with your doctor:

- if you have ulceration, bleeding or perforation of your stomach or intestinal
- if you are elderly
- if you have kidney or liver diseases
- if you are dehydrated
- if you have heart failure or heart disease
- if you need to undergo major surgical procedures which lead to hypovolaemia (decreased volume of circulating blood in the body)
- if you are suffering from dyspepsia (discomfort at the epigastric region due to digestion problem).

Meloxicam may cause severe skin reactions, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms may include skin rash, blisters and peel off. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

-Taking other medicines

Tel your doctor if you are taking any other medicines, including any that you buy without prescription from a pharmacy, supermarket or health food shop.

Some medicines when taken with MELOCAM TABLET may interfere with each other. These include:

- other NSAIDs, medicines used for pain relieve
- -oral anticoagulants, ticlopidine, systemically administered heparin, thrombolytics, medicines used for blood thinning
- lithium, medicine used for depression.
- methotrexate, medicine that used to treat rheumatoid arthritis, as well as some types of cancer
- contraception, methods or technique to prevent pregnancy
- diuretics, also known as water pill
- antihypertensive, medicine to treat high blood pressure
- cholestyramine, medicine helps in lower the cholesterol levels in blood.
- cyclosporine, medicines to prevent transplant rejection.

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking medication.

How to use MELOCAM TABLET

-How much to use

Osteoarthritis: 7.5mg daily. May be increased if necessary up to a maximum of 15mg daily.

Rheumatoid Arthritis: 15mg daily. The dose may be reduced to 7.5mg daily according to the therapeutic response.

Ankylosing Spondylitis: 15mg daily.

In patients with increased risks of adverse reactions, start with the dose of 7.5mg daily.

In dialysis patients with severe renal failure, the dose should not exceed 7.5mg daily.

The total daily dosage should not exceed 15mg.

-When to use it

The tablets should be taken with water or other fluid in conjunction with food.

-How long to use it

Please refer to doctor or pharmacist.

-If you forget to use it

If you miss a dose of MELOCAM TABLET, take it as soon as possible. If it is approaching time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

-If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using MELOCAM TABLET

-Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking MELOCAM TABLET.

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give this medicine to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Driving and using machines

Be careful driving or operating machinery until you know how MELOCAM TABLET affects you.

Side effects

Like all medicines, MELOCAM TABLET can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Stomach and intestine: Dyspepsia (indigestion), nausea, vomiting, abdominal pain, constipation, flatulence (excessive air in the body) and diarrhea, esophagitis (inflammation of the esophagus), gastroduodenal ulcer, stomach and intestinal bleeding. stomach and intestinal perforation, colitis (inflammation of the lining of the colon), hepatitis (inflammation of the liver), gastritis (inflammation of the lining of the stomach).

Hematological (Blood): anemia (condition caused by low red blood cell), disturbances of blood count, including differential white cell count, leukopenia (reduction of white blood cell) and thrombocytopenia (deficiency platelets in blood).

Concomitant administration of a potentially myelotoxic drug (medicine that inhibit or suppress the bone marrow function) in particular methotrexate, appears to be a predisposing factor to the onset of cytopenia (low number of blood cell).

Dermatological (Skin): pruritus (itching) and skin rash, stomatitis (inflammation of mucous membrane of mouth) and urticaria (hives), photosensitization, bullous reactions, erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis may develop.

Respiratory: asthma

Central Nervous System: lightheadedness and headache, vertigo (spinning sensation), tinnitus (ringing in the ear) and drowsiness, confusion and disorientation.

Cardiovascular: oedema (excessive watery fluid in body cavities), increase of blood pressure, palpitations (feeling of fast or irregular heart beat).

Genitourinary: Abnormal renal function parameters (increased serum creatinine and/or serum urea), acute kidney failure.

Vision Disorders: conjunctivitis (inflammation of the eye), visual disturbances including blurred vision.

Hypersensitivity Reactions: angio-oedema and immediate hypersensitivity reactions including anaphylactoid / anaphylactic reactions.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers—Reporting)

Storage and Disposal of MELOCAM TABLET

-Storage

Keep in airtight container. Store below 30°C, protect from light & moisture.

-Disposal

If your doctor or pharmacist tells you to stop using MELOCAM TABLET or the batch has passed the expiry date, ask your doctor or pharmacist what to do with any that is left over.

Product description

-What it looks like

A round light yellow snap tablet, one side impressed with "(\$\frac{\sp}{75}\)" and other side is blank.

-Ingredients

-Active ingredient:

Meloxicam

-Inactive ingredient:

Cellulose

Silicon Dioxide

Sodium Starch Glycolate

Lactose

Magnesium Stearate

Povidone

Sodium Citrate

<u>-MAL number</u> MAL06051310AZ

Manufacturer

Y.S.P. Industries (M) Sdn. Bhd. Lot 3, 5 & 7, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor Darul Ehsan, Malaysia.

Product Registration Holder

Y.S.P. Industries (M) Sdn. Bhd. Lot 3, 5 & 7, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor Darul Ehsan, Malaysia.

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