

APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET _____

Read all of this leaflet carefully before you start taking this medicine.

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

SCHEDULING STATUS S₃

PROPRIETARY NAME (and dosage form):

Mobic® 7,5 mg

ABCD

Mobic® 15 mg

tablets

Meloxicam

1. WHAT MOBIC TABLETS CONTAIN

- The active substance is meloxicam (mel-ox-i-kam).
Each MOBIC 7,5 mg tablet contains 7,5 mg meloxicam.
Each MOBIC 15 mg tablet contains 15 mg meloxicam.
- The other ingredients are sodium citrate dihydrate, lactose monohydrate, microcrystalline cellulose, polyvinylpyrrolidone, silicon dioxide, magnesium stearate.
Sugar free.

2. WHAT MOBIC TABLETS ARE USED FOR

MOBIC is used to relieve symptoms of arthritis such as joint pain and inflammation in patients over 12 years of age. It is also used for the symptomatic relief of acute episodes of sciatica (pain in the hip nerve).

Meloxicam belongs to a class of medicines called non-steroidal anti-inflammatories. These medicines are usually used to treat inflammation, swelling, stiffness, pain and fever.

3. BEFORE USING MOBIC TABLETS

Do not use MOBIC tablets:

- if you are allergic to meloxicam or any of the other ingredients of MOBIC tablets
- if you are allergic to aspirin or other anti-inflammatory medicines
- if you have ever suffered from wheezing, nasal polyps (nasal obstruction due to swellings in the lining of your nose) along with a runny nose, swelling of the skin or urticaria (nettle rash) when taking aspirin or any other anti-inflammatory medicines
- if you have or have recently had a gastrointestinal ulcer (ulcer of the stomach or intestines), or perforation
- if you have active inflammatory bowel disease (Crohn's disease or ulcerative colitis)
- if you have serious liver disease
- if you have serious kidney disease and are not undergoing dialysis
- if you have any kind of established general bleeding disorder or have ever suffered from gastrointestinal bleeding (bleeding in the stomach or intestines) or cerebrovascular bleeding (bleeding in the brain)
- if you have uncontrolled heart failure
- if you have ever suffered from gastrointestinal bleeding (bleeding in the stomach or intestines) or perforation after taking aspirin or any other anti-inflammatory medicines
- if you are under the age of 12 years
- if you are pregnant, planning to become pregnant or if you are breastfeeding (**see Pregnancy and breastfeeding**)

Take special care with MOBIC tablets:

- Gastrointestinal bleeding or ulcer can occur at any time during treatment with MOBIC, with or without warning symptoms. Tell your doctor if you have ever suffered from oesophagitis (inflammation of the gullet) or gastritis (inflammation of the stomach) or any other gastrointestinal disease eg. ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia
- if you have high blood pressure
- if you have heart, liver or kidney disease
- if you have diabetes
- if you are elderly
- if you have hypovolaemia (reduced blood volume) which may occur if you have serious blood loss or burns, surgery or low fluid intake
- if you have ever been diagnosed with high potassium levels in the blood
- Note that MOBIC may reduce the contraceptive effectiveness of the intrauterine device (IUD)
- Tell your doctor if you develop any skin rash, sores on the linings of nose, mouth, etc., or other signs of allergy
- if you have been told by your doctor you have an intolerance to some sugars as this product contains lactose

Warnings:

MOBIC may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, previous stroke or think you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Taking MOBIC tablets with food and drink:

- The tablets should be swallowed with water or another drink, during a meal.
- Simultaneous intake of alcohol increases the risk of bleeding.
- This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Pregnancy and breastfeeding:

MOBIC should not be used during pregnancy or while breastfeeding.

If you are planning to become pregnant, if you think or know you are pregnant, or if you are breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

Visual disturbances, drowsiness and vertigo (sense of spinning) may occur with MOBIC. If affected do not drive or use machinery.

Taking other medicines with MOBIC tablets:

If you are taking other medicines on a regular basis, including medicines bought over the counter and complementary or traditional medicines, the use of MOBIC with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

MOBIC can interfere with other medicines such as:

- other non-steroidal anti-inflammatory drugs, including aspirin
- corticosteroids
- medicines which prevent blood clotting, eg. warfarin
- medicines which break down blood clots (thrombolytics)
- selective serotonin re-uptake inhibitors (used in the treatment of depression)
- lithium (a medicine mainly used to treat mood disorders)
- methotrexate (a medicine mainly used to treat tumours or severe uncontrolled skin conditions and active rheumatoid arthritis)
- any diuretic medicine (“water tablets”) – your doctor may monitor your kidney function if you are taking diuretics
- medicines used to treat high blood pressure
- probenecid (used to manage gout)

- cholestyramine (mainly used to lower cholesterol levels)
- cyclosporin (a medicine often used after organ transplants, or for severe skin conditions, rheumatoid arthritis or nephrotic syndrome)
- tacrolimus (a medicine often used after organ transplants)
- oral anti-diabetic medicines

Please consult your doctor, pharmacist or other healthcare professional for advice if you are a woman who uses an intrauterine contraceptive device (IUD) usually known as a coil.

It is best to ask your doctor or pharmacist for advice before you start taking any other medicine.

4. HOW TO USE MOBIC TABLETS

Follow your doctor's instructions about when and how to take your medicine and always read the label. The usual recommended doses are:

Rheumatoid arthritis:

15 mg (one x 15 mg tablet or two x 7,5 mg tablets) once per day. This may be reduced to 7,5 mg (one x 7,5 mg tablet) once per day, depending on the response.

Osteoarthritis:

7,5 mg (one x 7,5 mg tablet) once per day. This may be increased to 15 mg (one x 15 mg tablet or two x 7,5 mg tablets) once per day, if necessary.

Ankylosing spondylitis:

15 mg (one x 15 mg tablet or two x 7,5 mg tablets) once per day. This may be reduced to 7,5 mg (one x 7,5 mg tablet) once per day, depending on the response.

Episodes of acute sciatica:

7,5 mg (one x 7,5 mg tablet) once per day. This may be increased to 15 mg (one x 15 mg tablet or two x 7,5 mg tablets) once per day, if no improvement is seen.

The tablets should be swallowed with water or another drink, during a meal. If you need to take two x 7,5 mg tablets, they must be taken together as one single dose.

The total daily dosage of MOBIC administered as tablets, suppositories and injections should not exceed 15 mg. ***Do not exceed the recommended maximum dose of 15 mg meloxicam per day.***

If any of the statements listed under the heading 'Take special care with MOBIC tablets' apply to you, your doctor may restrict your dose to 7,5 mg once a day.

If you have the impression that the effect of MOBIC tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more MOBIC tablets than you should:

In the event of overdose, consult your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take MOBIC tablets, do **not** take a double dose to make up for the missed dose.

If after several days you do not feel any improvement in your condition then you should talk to your doctor or pharmacist.

Do not share medicines that are prescribed for you with others.

5. POSSIBLE SIDE-EFFECTS

MOBIC tablets can have side-effects. If any of these side-effects continue, are severe or bother you, tell your doctor or pharmacist.

MOBIC may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke.

The following side-effects have been reported, which may be related to the use of MOBIC :

More common (in 1-10 % of patients):

- gastrointestinal symptoms such as indigestion, feeling sick or being sick, abdominal pain or diarrhoea
- headache

Less common (between 0,1-1 % of patients):

- constipation, flatulence (wind), gastritis (a stomach problem which may result in pain, nausea, vomiting, vomiting blood, and blood in the bowel motions), burping
- gastrointestinal bleeding (causing offensive, tar-coloured stools)
- inflammation or soreness of the mouth
- bleeding
- anaemia
- skin rash, itching
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- vertigo (dizziness or spinning sensation)
- dizziness, somnolence (sleepiness or drowsiness)
- flushing, increase in blood pressure

- abnormalities in tests of liver function
- abnormalities in tests of kidney function, any changes in urination
- general oedema (swelling of face, feet or lower legs)

Although the following side-effects are rare or the frequency is unknown, if they do occur they need medical attention. Contact your doctor as soon as possible if you notice:

- stomach or intestinal ulcer
- inflammation of the large bowel (diarrhoea usually with bloody or black-coloured stools and mucous, stomach pain and fever)
- soreness of the gullet
- vomiting blood or material that looks like coffee grounds, Crohn's disease
- severe, persistent abdominal pain
- liver disease (with nausea, vomiting, loss of appetite, generally feeling unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine)
- abnormality of white blood cell or platelet numbers, unusual bleeding or bruising, sore throat, fever and chills
- severe skin reaction which may be associated with painful red areas, large blisters and peeling of layers of skin with fever and chills, aching muscles and generally feeling unwell, or severe blistering and bleeding in mucous membranes (lips, eyes, mouth, nose and genitals), urticaria (nettle rash)
- increased sun sensitivity
- asthma (difficulty in breathing) - seen in people who are allergic to aspirin or other non-steroidal anti-inflammatory medicines
- insomnia (trouble sleeping), nightmares
- confusion and disorientation, mood changes
- tinnitus (noises in the ear)
- unusual fast or irregular heartbeat or palpitations
- cardiac failure (disease of the heart with shortness of breath and swelling of face, feet or lower legs due to fluid build-up)
- sudden, life-threatening or severe allergic reactions which may include fainting, shortness of breath and skin reactions
- kidney disease where you pass little or no urine – other symptoms include drowsiness, nausea, vomiting and breathlessness
- visual disturbances including blurred vision, conjunctivitis (discharge with itching of the eyes)

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

If you notice any other effects, contact your doctor or pharmacist.

6. STORING AND DISPOSING OF MOBIC TABLETS

Store MOBIC tablets in a cool place.

Aluminium foil/white blister film pack: Store below 25 °C.

Aluminium foil/aluminium foil pack: Store below 30 °C.

Keep all medicines out of the reach and sight of children.

Do not take this medicine after the expiry date stated on the blister strips and carton. Return unused or expired medicines to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF MOBIC TABLETS

Cartons of 30 MOBIC 7,5 mg tablets packed in blister strips (either aluminium foil on one side /white blister film on the other, or aluminium foil on both sides).

Cartons of 10 or 30 MOBIC 15 mg tablets packed in blister strips (either aluminium foil on one side /white blister film on the other, or aluminium foil on both sides).

8. IDENTIFICATION OF MOBIC TABLETS

MOBIC 7,5 mg tablets are round, pastel yellow to lemon yellow tablets. One face is convex, has a bevelled edge and is impressed with the Company's symbol; the other face is impressed with the tablet code 59D and is scored across its entire diameter. The surface of the tablets may be slightly rough.

MOBIC 15 mg tablets are round, pastel yellow to lemon yellow tablets. One face is convex, has a bevelled edge and is impressed with the Company's symbol; the other face is impressed with the tablet code 77C and is scored across its entire diameter. The surface of the tablets may be slightly rough.

9. REGISTRATION NUMBERS

MOBIC 7,5 mg tablets: 29/3.1/0421

MOBIC 15 mg tablets: 29/3.1/0422

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

15 April 2011