

PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Mobic® 7,5 mg Mobic® 15 mg tablets

Meloxicam



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

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

The active substance is meloxicam.

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, lactose monohydrate, microcrystalline cellulose, povidone K25, colloidal anhydrous silica, crospovidone and magnesium stearate.

Contains sugar (MOBIC 7,5 mg tablets contain 23,5 mg lactose and MOBIC 15 mg tablets contain 20 mg lactose (as monohydrate)).

2. WHAT MOBIC TABLETS ARE USED FOR

MOBIC is used in patients aged 12 years and older to relieve symptoms of arthritis such as joint pain and inflammation. It is also used for the symptomatic relief of acute episodes of sciatica (pain in the hip nerve) and ankylosing spondylitis (an inflammatory disease that can cause some of the vertebrae in your spine to fuse together).

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 YOU TAKE MOBIC TABLETS

Do not take 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 (asthma), 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 had a recurring gastrointestinal ulcer (ulcer of the stomach or intestines), perforation or bleeding
- if you have active inflammatory bowel disease (Crohn's disease or ulcerative colitis)
- if you have severe liver disease
- if you have severe kidney disease and are not undergoing dialysis
- if you have any kind of established general bleeding disorder or gastrointestinal bleeding (bleeding in the stomach or intestines) or recent cerebrovascular bleeding (bleeding in the brain)
- if you have heart failure (i.e. when your heart inadequately pumps blood through the body)
- if you have ever suffered from gastrointestinal bleeding (bleeding in the stomach or intestines), ulceration or perforation after taking aspirin or any other anti-inflammatory medicines, including MOBIC
- 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)
- if you have had coronary artery bypass graft (CABG) surgery, since MOBIC should not be used to treat pain after such an operation
- if you have been told by your doctor that you have an intolerance to some sugars, as MOBIC contains lactose (as monohydrate) (see Important information about some of the ingredients of MOBIC)

Take special care with MOBIC tablets and tell your healthcare provider:

- If you are elderly, side effects may happen more often, especially bleeding in the stomach and intestines, ulceration or perforation (which may be fatal), and you should discuss this with your doctor
- 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 e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastroesophageal reflux disease or angiodysplasia (a small malformation of some blood vessels in the gut)
- Tell your doctor if you are taking anticoagulant medicines (to prevent blood clotting)
- Tell your doctor if you develop any skin rash, sores on the linings of nose, mouth, etc., or other signs of allergy like swollen lymph glands or fever
- Tell your doctor if you have heart disease, high blood pressure, diabetes, high cholesterol or if you are a smoker as these may increase the risk of heart attack or stroke
- Tell your doctor if you have liver or kidney disease
- You should tell your doctor if you have hypovolaemia (reduced blood volume) which may occur if you have serious blood loss or burns, surgery or low fluid intake, or if you are taking diuretics (water tablets) or certain medications used to treat high blood pressure

- Tell your doctor if you have ever been diagnosed with high sodium or potassium levels in the blood, or if you are retaining water (swollen hands or feet)
- MOBIC may reduce the contraceptive effectiveness of the intrauterine device (IUD) (see Taking other medicines with MOBIC tablets), and you should take additional precautions to avoid falling pregnant
- MOBIC 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 you have heart problems, have had a 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 if you are a smoker) you should discuss your treatment with your doctor or pharmacist
- The regular use of MOBIC 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
- MOBIC may mask the symptoms of an infection.

Taking MOBIC tablets with food and drink:

- Swallow the tablets as a single dose with water or another drink, during a meal.
- Simultaneous intake of alcohol increases the risk of bleeding.

Pregnancy and breastfeeding:

You should not use MOBIC during pregnancy or while breastfeeding.

MOBIC may affect a woman’s ability to fall pregnant as it may delay ovulation.

If you are planning to become pregnant, if you think or know you are pregnant, or if you are breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking MOBIC.

Driving and using machinery:

Visual disturbances including blurred vision, drowsiness, dizziness and vertigo (a sense of spinning) may occur with MOBIC. If you are affected do not drive or use machinery.

Important information about some of the ingredients of MOBIC:

MOBIC 7,5 mg tablets contain 47 mg lactose per maximum recommended daily dose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take MOBIC.

MOBIC 15 mg tablets contain 20 mg lactose per maximum recommended daily dose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take MOBIC.

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

Taking other medicines with MOBIC tablets:

Always tell your healthcare professional if you are taking any other medicine. 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 medicines, including aspirin
- corticosteroids, which may increase the risk of gastrointestinal perforation, ulceration or bleeding
- medicines which prevent blood clotting (anticoagulants), e.g. warfarin, heparin and anti-platelet medicines, e.g. clopidogrel
- 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)
- ciclosporin (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)
- pemetrexed (a medicine used to treat certain types of cancer)
- oral anti-diabetic medicines such as sulphonylureas and nateglinide.

Simultaneous intake of alcohol increases the risk of bleeding.

MOBIC may reduce the contraceptive effectiveness of the intrauterine device (IUD). 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 TAKE MOBIC TABLETS

Do not share medicines prescribed for you with any other person.

Always take MOBIC exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual recommended doses are:

Rheumatoid arthritis:

15 mg (one x 15 mg tablet or two x 7,5 mg tablets) once per day. Your doctor may reduce this to 7,5 mg (one x 7,5 mg tablet) once per day, depending on the response.

Painful osteoarthritis:

7,5 mg (one x 7,5 mg tablet) once per day. Your doctor may increase this 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. Your doctor may reduce this 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. Your doctor may increase this to 15 mg (one x 15 mg tablet or two x 7,5 mg tablets) once per day, if no improvement is seen.

Swallow the tablets with water or another drink, during a meal. If you need to take two x 7,5 mg tablets, you should take them together as one single dose.

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

It is important to tell your doctor if you suffer from kidney problems, have a history of gastrointestinal disease or risk factors for heart disease (e.g. high blood pressure, diabetes, high cholesterol or if you are a smoker), as you should receive the lower dose of 7,5 mg MOBIC per day. See "Take special care with MOBIC tablets and tell your healthcare provider".

Your doctor will tell you how long your treatment with MOBIC will last.

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

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

If you take more MOBIC tablets than you should:

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

If you forget to take MOBIC tablets:

Take your dose when you remember. Do not take a double dose to make up for the missed dose.

5. POSSIBLE SIDE EFFECTS

MOBIC tablets can have side effects.

If you experience any of the following very serious side effects, stop taking MOBIC and tell your doctor immediately or go to the casualty department at your nearest hospital.

- sudden, life-threatening or severe allergic reactions which may include fainting, shortness of breath, skin reactions, swollen lymph glands and fever.
- MOBIC may be associated with an increased risk of heart attack (“myocardial infarction”) or stroke. Symptoms may include chest pain, shortness of breath, weakness and slurring of speech.

If the following side effects occur, they also need medical attention. Contact your doctor as soon as possible or go to the casualty department at your nearest hospital if you notice:

- asthma (difficulty in breathing) - seen in people who are allergic to aspirin or other non-steroidal anti-inflammatory medicines
- 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
- severe, persistent abdominal pain
- 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)
- cardiac failure (disease of the heart with shortness of breath and swelling of face, feet or lower legs due to fluid build-up)
- unusual fast or irregular heartbeat or palpitations
- abnormality of white blood cell or platelet numbers, unusual bleeding or bruising, sore throat, fever and chills
- liver disease (with nausea, vomiting, loss of appetite, generally feeling unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine)
- kidney disease where you pass little or no urine – other symptoms include drowsiness, nausea, vomiting and breathlessness
- confusion and disorientation, mood changes

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

Frequent:

- gastrointestinal symptoms such as indigestion, nausea (feeling sick) or vomiting (being sick), abdominal pain or diarrhoea
- headache

Less frequent:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing

- asthma (difficulty in breathing) in persons allergic to aspirin or other non-steroidal anti-inflammatory medicines
- 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 or vomiting blood)
- 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
- bleeding
- anaemia, changes in blood count test results (including low white cell count), unusual bleeding or bruising, sore throat, fever and chills
- skin reactions which may be severe, skin rash, itching, which may be accompanied by yellowing of the whites of the eyes and skin and darkened urine
- palpitations, heart failure
- general oedema (swelling of face, feet or lower legs)
- increase in blood pressure (high blood pressure)
- flushing
- abnormalities in tests of liver function
- abnormalities in tests of kidney function, any changes in urination
- vertigo (dizziness or spinning sensation), tinnitus (noises in the ear)
- dizziness, somnolence (sleepiness or drowsiness), insomnia (sleeplessness), nightmares
- altered mood, confusion and disorientation
- visual disturbances including blurred vision, conjunctivitis (discharge with itching of the eyes)
- increased sun sensitivity
- delayed ovulation and infertility in females

If any of these side effects continue, are severe or bother you, tell your doctor or pharmacist.

Not all side effects reported for MOBIC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MOBIC, please consult your doctor, pharmacist, or other healthcare professional for advice.

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

6. STORING AND DISPOSING OF MOBIC TABLETS

Store at or 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 aluminium foil blister strips.
Cartons of 10 or 30 MOBIC 15 mg tablets packed in aluminium foil blister strips.

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

Ingelheim Pharmaceuticals (Pty) Ltd

407 Pine Avenue

Randburg

South Africa

Tel No.: + 27-11-348-2400

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date of registration: 11 November 1995 (MOBIC 7,5 mg); 05 March 1997 (MOBIC 15 mg)

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