PACKAGE LEAFLET: INFORMATION FOR THE USER

MOBIC®

7.5 mg and 15 mg tablets

Meloxicam

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 any further 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What MOBIC is and what it is used for

MOBIC contains the active substance meloxicam. Meloxicam belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs) which are used to reduce inflammation and pain in joints and muscles.

MOBIC tablets are indicated in adults and children aged 16 years and older.
MOBIC is used for the:

- short-term treatment of flare-ups of osteoarthritis
- long-term treatment of
    - rheumatoid arthritis
    - ankylosing spondylitis

2. What you need to know before you take MOBIC

Do not take MOBIC:

- if you are allergic to meloxicam or any of the other ingredients of this medicine (listed in section 6)
- during the last three months of pregnancy
- children and adolescents below 16 years of age
- any of the following signs after taking aspirin or other NSAIDs:
    - wheezing, chest tightness, breathlessness (asthma)
    - nasal blockage due to swellings in the lining in your nose (nasal polyps)
    - skin rashes/nettle rash (urticaria)
    - sudden skin or mucosal swelling, such as swelling around the eyes, face, lips, mouth or throat, possibly making breathing difficult (angio-oedema)
- after previous therapy with NSAIDs and history of

    - bleeding in your stomach or intestines
    - holes (perforations) in your stomach or intestines
- ulcers or a bleeding in your stomach or intestines
- recent or history of stomach or peptic ulcers or bleeding (ulceration or bleeding occurring at least twice)
- severely impaired liver function
- non dialysed severe kidney failure
- recent bleeding in the brain (cerebrovascular bleeding)
- any kind of bleeding disorders
- severe heart failure
- intolerance to some sugars as this product contains lactose (see also "MOBIC contains milk sugar (lactose) and sodium")
- perioperative pain in the setting of the coronary artery bypass graft (CAPG) surgery.

If you are unsure whether any of the above applies to you, please contact your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking MOBIC.

Warnings

Medicines such as MOBIC may be associated with a small increased risk of heart attack (myocardial infarction) or stroke (apoplexy). Any risk is more likely with high doses and prolonged treatment. Do not take more than the recommended dose. Do not take MOBIC for longer than it is prescribed for you (see section 3 "How to take MOBIC").

If you have heart problems, previous stroke or think that you might be at risk of these conditions, you should discuss your treatment with your doctor or pharmacist. For example if you:
- have high blood pressure (hypertension)
- have high levels of sugar in the blood (diabetes mellitus)
- have high levels of cholesterol in the blood (hypercholesterolemia)
- are a smoker

Stop your treatment with MOBIC immediately as soon as you notice bleeding (causing tar-coloured stools) or ulceration of your digestive tract (causing abdominal pain).

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of MOBIC, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.
The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.
If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of MOBIC, you must not be re-started on MOBIC at any time.
If you develop a rash or these skin symptoms, stop taking MOBIC, seek urgent advice from a doctor and tell him that you are taking this medicine.

MOBIC is not appropriate, if you require immediate relief from acute pain.

MOBIC may hide the symptoms of infection (e.g. fever). If you think you may have an infection you should see your doctor.

Precautions for use

As it will be necessary to adjust the treatment, it is important to ask your doctor's advice before you take MOBIC in case of:

- history of inflammation of the gullet (oesophagitis), inflammation of the stomach (gastritis) or a history of any other disease of the digestive tract, e.g. Crohn's Disease or Ulcerative Colitis
- high blood pressure (hypertension)
- older age
- heart, liver or kidney disease
- high levels of sugar in the blood (diabetes mellitus)
- reduced blood volume (hypovolaemia) which may occur if you have a serious blood loss or burn, surgery or low fluid intake
- intolerance to some sugars diagnosed by your doctor as this product contains lactose
- high potassium levels in the blood previously diagnosed by your doctor

Your doctor will need to monitor your progress whilst on treatment.

Other medicines and MOBIC

As MOBIC may affect or be affected by other medicines, tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular please tell your doctor or pharmacist if you are taking/have taken, or are using any of the following:

- other NSAIDs
- potassium salts – used to prevent or to treat low blood levels of potassium
- tacrolimus – used after organ transplants
- trimethoprim – used in the treatment of urinary tract infections
- medicines which prevent blood clotting
- medicines which break down blood clots (thrombolytics)
- medicines to treat heart and kidney diseases
- corticosteroids (e.g. used against inflammation or allergic reactions)
- cyclosporin – used after organ transplants, or for severe skin conditions, rheumatoid arthritis or nephrotic syndrome
- deferasirox – used to treat chronic iron overload due to frequent blood transfusions
- any diuretic medicine ("water tablets")
  Your doctor may monitor your kidney function if you are taking diuretics.
- medicine to treat high blood pressure (e.g. Beta-blockers)
- lithium – used to treat mood disorders
- selective Serotonin re-uptake inhibitors (SSRIs) – used in the treatment of depression
- methotrexate – used to treat tumours or severe uncontrolled skin conditions and active rheumatoid arthritis
- pemetrexed – used in the treatment of cancer
- cholestyramine – used to lower cholesterol levels
- oral antidiabetics (sulphonylureas, nateglinide) – used in the treatment of diabetics. Your doctor should carefully monitor your level of blood sugar for hypoglycemia.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
Do not take MOBIC if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.
You should not take MOBIC during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, MOBIC can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.
If you have taken this medicine while you were pregnant, you must immediately talk to your doctor/midwife so that adequate monitoring can be considered.

Breast-feeding
This product is not recommended during breast feeding.

Fertility
This product may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines
Visual disturbances, including blurred vision, dizziness, drowsiness, vertigo or other central nervous system disturbances may occur with this product. If affected do not drive or operate machinery.

MOBIC contains milk sugar (lactose) and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take MOBIC
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for MOBIC 7.5 mg is:

Flare-ups of osteoarthritis:
7.5 mg (one tablet) once a day. This may be increased to 15 mg (two tablets) once a day.

Rheumatoid arthritis:
15 mg (two tablets) once a day. This may be reduced to 7.5 mg (one tablet) once a day.

Ankylosing spondylitis:
15 mg (two tablets) once a day. This may be reduced to 7.5 mg (one tablet) once a day.

Do not exceed the recommended maximum dose of 15 mg a day.

If any of the statements listed under the heading "**Warnings and precautions**" apply to you, your doctor may restrict your dose to 7.5 mg (one tablet) once a day.

The recommended dose for MOBIC 15 mg is:

Flare-ups of osteoarthritis:
7.5 mg (half a tablet) once a day. This may be increased to 15 mg (one tablet) once a day.

Rheumatoid arthritis:
15 mg (one tablet) once a day. This may be reduced to 7.5 mg (half a tablet) once a day.

Ankylosing spondylitis:
15 mg (one tablet) once a day. This may be reduced to 7.5 mg (half a tablet) once a day.

Do not exceed the recommended maximum dose of 15 mg a day.

If any of the statements listed under the heading "**Warnings and precautions**" apply to you, your doctor may restrict your dose to 7.5 mg (half a tablet) once a day.

Elderly
If you are of an older age the recommended dose for long term treatment of rheumatoid arthritis and ankylosing spondylitis is 7.5 mg (one tablet of Mobic 7.5 mg or half a tablet of Mobic 15 mg) per day.

Patients with increased risks for adverse reaction
If you are a patient with an increased risk for adverse reactions, your doctor will start the treatment at a dose of 7.5 mg (one tablet of MOBIC 7.5 mg or half a tablet of MOBIC 15 mg) per day.

Renal impairment
If you are a dialysis patient with severe renal impairment, your dose should not exceed 7.5 mg (one tablet of MOBIC 7.5 mg or half a tablet of MOBIC 15 mg) per day.
No dose reduction is required in patients with mild to moderate renal impairment.

Hepatic impairment
No dose reduction is required in patients with mild to moderate hepatic impairment.

Use in children and adolescents
MOBIC should not be given to children and adolescents below 16 years of age.

If you feel that the effect of MOBIC is too strong or too weak, or if after several days you do not feel any improvement in your condition, talk to your doctor or pharmacist.

Method of administration
Oral use.
The tablets should be swallowed with water or another drink, during a meal.

The score line of MOBIC 7.5 mg is only there to help you break the tablet if you have difficulty swallowing it whole.

MOBIC 15 mg tablet can be divided into equal doses. The tablet should be divided by hand and not by a sharp object (e.g. a knife).

If you take more MOBIC than you should

Whether you have taken too many tablets or suspect an overdose, contact your doctor or go to your nearest hospital immediately.

Symptoms following acute NSAID overdose are usually limited to:

- lack of energy (lethargy)
- drowsiness
- feeling sick (nausea) and being sick (vomiting)
- pain in the area of the stomach (epigastric pain)

These symptoms generally get better when you stop taking MOBIC. You may suffer from bleeding of the stomach or intestines (gastrointestinal bleeding).

Severe poisoning may result in serious drug reaction (see section 4.):
- high blood pressure (hypertension)
- acute kidney (renal) failure
- liver (hepatic) dysfunction
- reduction/flattening or standstill of breathing (respiratory depression)
- loss of consciousness (coma)
- seizures (convulsions)
- collapse of the blood circulation (cardiovascular collapse)
- standstill of the heart (cardiac arrest)
- immediate allergic (hypersensitivity) reactions, including:
    - fainting
    - shortness of breath
    - skin reactions

If you forget to take MOBIC

Do not take a double dose to make up for a forgotten dose. Just take the next dose at the usual time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking MOBIC and consult a doctor or your nearest hospital immediately if you notice:

Any allergic (hypersensitivity) reactions, which may appear in the form of:
- skin reactions, such as itching (pruritus), blistering or peeling of the skin, which can be potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis), lesions of soft tissues (mucosal lesions) or erythema multiforme (see section 2).
  Erythema multiforme is a serious allergic skin reaction causing spots, red welts or purple or blistered areas. It can also affect the mouth, eyes and other moist body surfaces.
- swelling of skin or mucosa, such as swelling around the eyes, face and lips, mouth or throat, possibly making breathing difficult, swollen ankles or legs (oedema of the lower limbs)
- shortness of breath or asthma attack
- inflammation of the liver (hepatitis). This can cause symptoms such as:
    - yellowing of the skin or the eyeballs (jaundice)
    - pain in the abdomen
    - loss of appetite

Any side effects of the digestive tract, especially:
- bleeding (causing tar-coloured stools)
- ulceration of your digestive tract (causing abdominal pain)

Bleeding of the digestive tract (gastrointestinal bleeding), formation of ulcers or formation of a hole in the digestive tract (perforation) may sometimes be severe and potentially fatal, especially in elderly.

If you have previously suffered from any symptoms of the digestive tract due to long term use of NSAIDs, seek medical advice immediately, especially if you are elderly. Your doctor may monitor your progress whilst on treatment.

If affected by visual disturbances do not drive or operate machinery.

General side effects of non-steroidal anti-inflammatory medicines (NSAIDs)

The use of some non-steroidal anti-inflammatory drugs (NSAIDs) may be associated with a small increased risk of occlusion of arterial vessels (arterial thrombotic events), e.g. heart attack (myocardial infarction) or stroke (apoplexy), particularly at high doses and in long term treatment.

Fluid retention (oedema), high blood pressure (hypertension) and heart failure (cardiac failure) have been reported in association with NSAID treatment.

The most commonly-observed side effects affect the digestive tract (gastrointestinal events):
- ulcers of the stomach and upper part of the small bowels (peptic /gastroduodenal ulcers)
- a hole in the wall of the bowels (perforation) or bleeding of the digestive tract (sometimes fatal, particularly in the elderly)

The following side effects have been reported after NSAID administration:
- feeling sick (nausea) and being sick (vomiting)
- loose stools (diarrhoea)
- flatulence
- constipation
- indigestion (dyspepsia)
- abdominal pain
- tar-coloured stool due to bleeding in the digestive tract (melaena)
- vomiting of blood (haematemesis)
- inflammation with building of ulcers in the mouth (ulcerative stomatitis)
- worsening of inflammation of the digestive tract (e.g. exacerbation of colitis or Crohn's disease)

Less frequently, inflammation of the stomach (gastritis) has been observed.

Side effects of meloxicam – the active substance of MOBIC

Very common: may affect more than 1 in 10 people
- gastrointestinal adverse events such as indigestion (dyspepsia), feeling sick (nausea) and being sick (vomiting), abdominal pain, constipation, flatulence, loose stools (diarrhoea)

Common: may affect up to 1 in 10 people
- headache

Uncommon: may affect up to 1 in 100 people
- dizziness (light-headedness)
- a feeling of dizziness or spinning (vertigo)
- somnolence (drowsiness)
- anaemia (reduction of the concentration of the red blood pigment haemoglobin)
- increase in blood pressure (hypertension)
- flushing (temporary redness of the face and neck)
- sodium and water retention

- increased potassium levels (hyperkalaemia). This can lead to symptoms such as:
    - changes to your heartbeat (arrythmias)
    - palpitations (when you feel your heartbeat more than usual)
    - muscle weakness
- eructation
- inflammation of the stomach (gastritis)
- bleeding of the digestive tract
- inflammation of the mouth (stomatitis)
- immediate allergic (hypersensitivity) reactions
- itching (pruritus)
- skin rash
- swelling caused by fluid retention (oedema), including swollen ankles/legs (oedema of the lower limbs)
- sudden skin or mucosal swelling, such as swelling around the eyes, face, lips, mouth or throat, possibly making breathing difficult (angio-oedema)
- momentary disturbance of liver function tests (e.g. raised liver enzymes like transaminases or an increase of the bile pigment bilirubin). Your doctor can detect these using a blood test.
- disturbance of laboratory tests investigating kidney (renal) function (e.g. raised creatinine or urea)

Rare: may affect up to 1in 1,000 people
- mood disorders
- nightmares
- abnormal blood count, including:
    - abnormal differential blood count
    - decreased number of white blood cells (leucocytopenia)
    - decreased number of blood platelets (thrombocytopenia)

  These side effects may lead to increased risk of infection and symptoms such as bruising or nosebleeds.
- ringing in the ear (tinnitus)
- feeling your heartbeat (palpitations)
- ulcers of the stomach or upper part of the small bowels (peptic /gastroduodenal ulcers)
- inflammation of the gullet (oesophagitis)
- onset of asthma attacks (seen in people who are allergic to aspirin or other NSAIDs)
- severe blistering of the skin or peeling (Stevens-Johnson Syndrome and toxic epidermal necrolysis)
- nettle rash (urticaria)
- visual disturbances including:
    - blurred vision
    - conjunctivitis (inflammation of the eyeball or eyelids)
- inflammation of the large bowel (colitis)

Very rare: may affect up to 1 in 10,000 people
- blistering reactions of the skin (bullous reactions) and erythema multiforme.
  Erythema multiforme is a serious allergic skin reaction causing spots, red welts or purple or blistered areas. It can also affect the mouth, eyes and other moist body surfaces.
- inflammation of the liver (hepatitis). This can cause symptoms such as:
    - yellowing of the skin or the eyeballs (jaundice)
    - pain of the abdomen
    - loss of appetite
- acute failure of the kidneys (renal failure) in particular in patients with risk factors such as heart disease, diabetes or kidney disease.
- a hole in the wall of the bowels (perforation)

Not known: frequency cannot be estimated from the available data
- confusion
- disorientation

shortness of breath and skin reactions (anaphylactic/anaphylactoid reactions) rashes caused by exposure to sunlight (photosensitivity reactions)
- heart failure (cardiac failure) has been reported in association with NSAID treatment
- complete loss of specific types of white blood cells (agranulocytosis), especially in patients who take MOBIC together with other drugs that are potentially inhibitory, depressant or destructive to a component of the bone marrow (myelotoxic drugs). This can cause:
    - sudden fever
    - sore throat
    - infections
- inflammation of the pancreas (pancreatitis)
- infertility in woman, ovulation delay

Side effects caused by non-steroidal anti-inflammatory medicines (NSAIDs), but not yet seen after taking MOBIC

Changes to the kidney structure resulting in acute kidney failure:
- very rare cases of kidney inflammation (interstitial nephritis)
- death of some of the cells within the kidney (acute tubular or papillary necrosis)
- protein in the urine (nephrotic syndrome with proteinuria)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 MOBIC

Store in safe place.

Do not store above 30ºC.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister strip and outer carton. The expiry date refers to the last day of that month.

Store in the original package to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What MOBIC contains

The active substance is:

- meloxicam
- one tablet of MOBIC 7.5 mg contains 7.5 mg meloxicam.
- one tablet of MOBIC 15 mg contains 15 mg meloxicam.

The other ingredients are:

- sodium citrate
- lactose monohydrate
- microcrystalline cellulose
- povidone K25
- anhydrous colloidal silica
- crospovidone
- magnesium stearate

What MOBIC looks like and contents of the pack

MOBIC 7.5 mg is a light yellow, round tablet with the company logo on one side and 59D/59D on the other side. Each MOBIC 7.5 mg tablet has a score line. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

MOBIC 15 mg is a light yellow, round tablet with the company logo on one side and 77C/77C on the other side. Each MOBIC 15 mg tablet has a score line and can be divided into two equal halves.

MOBIC is available in Aluminium/ Aluminum blister packs.

Pack sizes:

Mobic 7.5 mg Packs of 1, 2, 7, 10, 14, 15, 20, 28, 30, 50, 60, 100, 140, 280, 300, 500, 1000 tablets.

Mobic 15 mg Packs of 1, 2, 7, 10, 14, 15, 20, 28, 30, 50, 60, 100, 140, 280, 300, 500, 1000 tablets.

Not all pack sizes are registered or marketed in your country.

Other strengths of MOBIC and other ways to take meloxicam

In some countries meloxicam is also available as:

- meloxicam 15 mg per 1.5 mL solution for injection

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Boehringer Ingelheim International GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Manufacturer and Batch release site

Rottendorf Pharma GmbH
Ostenfelder Straße 51- 61
59320 Ennigerloh
Germany

Primary and secondary packaging site

Rottendorf Pharma GmbH
Am Fleigendahl 3,
59320 Ennigerloh,
Germany

This leaflet was last revised in Oct 2022.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Boehringer Ingelheim
Middle East & North Africa
Tel: +971 (4) 423 0400
Fax: +971 (4) 423 3637

This is a Medicament

− Medicament is a product which affects your health and its consumption contrary to an instruction is dangerous for you.
− Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
− The doctor and the pharmacist are the experts in medicines, their benefits and risks.
− Do not by yourself interrupt the period of treatment prescribed for you.
− Do not repeat the same prescription without consulting your doctor.
− Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists