

## PATIENT INFORMATION LEAFLET

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**SCHEDULING STATUS: S3**

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

**Mobic® 15 mg/1,5 mL**

**abcd**

injection

Meloxicam

**Read all of this leaflet carefully before MOBIC 15 mg/1,5 mL injection is administered to you.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- MOBIC 15 mg/1,5 mL injection 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 15 mg/1,5 mL INJECTION CONTAINS**

- The active substance is meloxicam (mel-ox-i-kam).  
Each ampoule of 1,5 mL contains 15 mg meloxicam.
- The other ingredients are glycine, glycofurol, meglumine, poloxamer 188, sodium chloride, sodium hydroxide, water for injection. Sugar free.

### **2. WHAT MOBIC 15 mg/1,5 mL INJECTION IS USED FOR**

MOBIC 15 mg/1,5 mL injection is used for the short-term relief of symptoms of flare ups of arthritis and ankylosing spondylitis such as joint pain and inflammation in patients over 18 years of age. It is also used for the short-term 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 MOBIC 15 mg/1,5 mL INJECTION IS ADMINISTERED TO YOU**

**Do not have MOBIC 15 mg/1,5 mL injection administered:**

- if you are allergic to meloxicam or any of the other ingredients of MOBIC injection
- 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 are taking medicines which prevent blood clotting (anticoagulants)

- 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 18 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.

**Take special care with MOBIC 15 mg/1,5 mL injection and tell your doctor or healthcare professional before being given the injection:**

- 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 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 15 mg/1,5 mL injection), 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. Any 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
- Tell your doctor if you are taking lithium (a medicine mainly used to treat mood disorders)

**Receiving MOBIC 15 mg/1,5 mL injection with food and drink:**

Simultaneous intake of alcohol increases the risk of bleeding.

**Pregnancy and breastfeeding:**

You should not use MOBIC during pregnancy or while breastfeeding.

MOBIC injection should not be administered if you are attempting to fall pregnant as MOBIC may impair ovulation and fertility.

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

Mothers receiving MOBIC should not breastfeed their babies.

**Driving and using machinery:**

You should be careful as visual disturbances including blurred vision, dizziness, drowsiness and vertigo (sense of spinning) may occur with MOBIC. If affected do not drive or use machinery.

**Taking other medicines with MOBIC 15 mg/1,5 mL injection:**

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, e.g. warfarin and antiplatelet medicines, e.g. clopidogrel. (See You should not have MOBIC 15 mg/1,5 mL injection administered)
- 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)
- 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 intra-uterine 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 RECEIVE MOBIC 15 mg/1,5 mL INJECTION**

You will not be expected to give yourself MOBIC injection. It will be administered to you by a healthcare professional who is qualified to do so by deep intramuscular injection in a dose of 7,5 mg to 15 mg once daily. ***MOBIC injection should not be administered intravenously.***

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 15 mg/1,5 mL Injection).

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

MOBIC injection must not be used for longer than 3 days, thereafter treatment can be continued with MOBIC tablets if necessary. A total daily dose of 15 mg meloxicam per day should not be exceeded regardless of formulation.

#### **If you receive more MOBIC injection than you should:**

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

#### **5. POSSIBLE SIDE EFFECTS**

MOBIC injection can have side effects.

If you experience any of the following very serious side effects, 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
- swelling and pain at the injection site

**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, 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)
- 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 injection are included in this leaflet. Should your general health worsen while receiving MOBIC injection, please consult your doctor, pharmacist, or other healthcare professional for advice.

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

## **6. STORING AND DISPOSING OF MOBIC 15 mg/1,5 mL INJECTION**

Store MOBIC injection in a cool place (at or below 30 °C).

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

Do not use this medicine after the expiry date stated on the ampoule label 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 15 mg/1,5 mL INJECTION**

Packs of 5 ampoules.

## **8. IDENTIFICATION OF MOBIC 15 mg/1,5 mL INJECTION**

MOBIC 15 mg/1,5 mL injection is a clear, yellow solution with a green tinge, contained in colourless glass ampoules.

## **9. REGISTRATION NUMBER**

29/3.1/0420

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

Ingelheim Pharmaceuticals (Pty) Ltd

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**11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET**

Date of registration: 20 August 1999

Revised: 13 December 2021