PACKAGE LEAFLET: INFORMATION FOR THE USER
MEFSAL® 7.5 mg tablets
MEFSAL® 15 mg scored tablets
Meloxicam

Read all of this leaflet carefully before you start taking this medicine.
It contains important information about your treatment and illness.
If you have any further questions, ask your doctor or pharmacist.
Keep this leaflet. You may need to read it again.

I. IDENTIFICATION OF THE MEDICINAL PRODUCT:

Form / presentation:
MEFSAL® 7.5 mg tablets, packs of 10 and 20
MEFSAL® 15 mg, scored tablets, packs of 10 and 20

Qualitative and quantitative composition
The active substance is Meloxicam.
MEFSAL® 7.5 mg tablets: 1 tablet contains 7.5 mg Meloxicam
MEFSAL® 15 mg scored tablets: 1 tablet contains 15 mg Meloxicam

	MEFSAL® 7.5mg	**MEFSAL® 15 mg**
	mg / tab	mg / scored tab
Active substance		
Meloxicam	7,5 mg	15 mg
Excipients	Pregelatinised starch (1500); Lactose monohydrate, Maize starch, Sodium citrate, Microcrystalline cellulose (Avicel pH 102), silica colloidal anhydrous and magnesium stearate q.s.p 1 Tablet.	

List of excipients with known effect: Lactose monohydrate

PHARMACO-THERAPEUTIC CLASS:
MEFSAL contains the active substance Meloxicam. Meloxicam belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) which are used to reduce inflammation and pain in joints and muscles.

II. WHAT MEFSAL IS AND WHAT IT IS USED FOR.

INDICATION:
MEFSAL is used for the:
- short-term treatment of flare-ups of osteoarthritis
- Long-term treatment of
  - rheumatoid arthritis
  - ankylosing spondylitis (also known as Bechterew's Disease)

III. IN WHICH CASES DO NOT USE THIS MEDICINE?

CONTRA-INDICATION:

Do not take MEFSAL if any of the following apply:

- during the last three months of pregnancy
- children and adolescents under 16 years of age
- allergy (hypersensitivity) to meloxicam
- allergy (hypersensitivity) to aspirin or other anti-inflammatory medicines (NSAlDs)
- allergy (hypersensitivity) to any of the other ingredients of MEFSAL. (See composition)
- any of the following signs after taking aspirin or other NSAlDs:
    - 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 (angioneuroticoedema)
- 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)
- serious liver disease
- serious kidney disease and not undergoing dialysis
- 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 composition of MEFSAL")

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

PRECAUTIONS FOR USE; SPECIAL WARNINGS:

Take special care with MEFSAL 7.5 mg tablet and 15 mg scored tablet:

Special warnings

Medicines such as MEFSAL 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 MEFSAL for longer than it is prescribed for you (see "How to take MEFSAL").

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

If you develop severe allergic reactions, you should discontinue MEFSAL at first appearance of skin rash, lesions of soft tissues (mucosal lesions), or any other sign of allergy, and contact your doctor.
Stop your treatment with MEFSAL immediately as soon as you notice bleeding (causing tar-coloured stools) or ulceration of your digestive tract (causing abdominal pain).
MEFSAL is not appropriate, if you require immediate relief from acute pain.
MEFSAL may hide the symptoms of infection (e.g. fever). If you think you may have an infection you should see your doctor.
MEFSAL may cause difficulties in pregnancy. You should tell your doctor if you are planning a pregnancy, or if you are having trouble getting pregnant.

Important information about some of the ingredients of MEFSAL
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.

Precautions for use:
As it will be necessary to adjust the treatment, it is important to ask your doctor's advice before you take MEFSAL 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 bum, 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.

INTERACTIONS WITH OTHER MEDICINES
Taking other medicines:
As MEFSAL may affect or be affected by other medicines, please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
In particular please tell your doctor or pharmacist if you are taking/have taken, or are using any of the following:
- other NSAIDs
- medicines which prevent blood clotting (e.g. anticoagulants)
- 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
- tacrolimus - used after organ transplants or for severe skin conditions
- diuretic medicine

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 (SSRls) - used in the treatment of depression
- methotrexate - used to treat tumours or severe uncontrolled skin conditions and active rheumatoid arthritis
- cholestyramine - used to lower cholesterol levels
- if you are a woman who uses an intrauterine contraceptive device (IUD), usually known as a coil

If in doubt, ask your doctor or pharmacist.

PREGNANCY AND BREAST FEEDING :

Pregnancy

If you become pregnant whilst using MEFSAL, you should tell your doctor. During the first 6 months of pregnancy only, your doctor may prescribe you this medical product if necessary.

During the last three months of pregnancy do not use this product, because MEFSAL can have serious effects on your unborn child, in particular heart, lung and kidney effects, even with only one dose.

Breast-feeding

This product is not recommended during breast-feeding.
Ask your doctor or pharmacist for advice before taking any medicine.

SPORTS:

Not applicable

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.

IV. HOW TO TAKE MEFSAL TABLETS.

- Posology, Mode and / or route (s) of administration, Frequency of administration and Duration of treatment:

Oral use

Always take MEFSAL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:
Flare-ups of osteoarthritis:
7.5 mg (i.e. one tablet of 7.5 mg or half a tablet of 15 mg) once daily. The dosage may be increased up to 15 mg (i.e. two tablets of 7.5 mg, or one tablet of 15 mg) once daily.

Rheumatoid arthritis:
15 mg (two 7.5 mg tablets or one 15 mg tablet) once daily. It may be reduced to 7.5 mg (one 7.5 mg tablet or half a 15 mg tablet) once daily.

Ankylosing spondylitis:
15 mg (two 7.5 mg tablets or one 15 mg tablet) once daily. It may be reduced to 7.5 mg (one 7.5 mg tablet or half a 15 mg tablet) once daily.

The tablets should be swallowed with water, or another drink, during a meal.

Do not exceed the recommended maximum dose of 15 mg a day.
If any of the statements listed under the heading "Take special care with MEFSAL" apply to you, your doctor may restrict your dose to 7.5 mg (i.e. one tablet of 7.5 mg or half a tablet of 15 mg) once daily.

MEFSAL should not be given to children and adolescents under 16 years of age.
If you feel that the effect of MEFSAL 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.

- Symptoms and instructions for overdose:
If you take more MEFSAL 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 MEFSAL. You may suffer from bleeding of the stomach or intestines (gastrointestinal bleeding).

Severe poisoning may result in serious drug reaction (see Side effects.):
- high blood pressure (hypertension)
- acute kidney (renal) failure

- liver (hepatic) dysfunction
- reduction/flattening or stopping of breathing (respiratory depression)
- loss of consciousness (coma)
- seizures (convulsions)
- collapse of the blood circulation (cardiovascular collapse)
- stopping of the heart (cardiac arrest)
- immediate allergic (hypersensitivity) reactions, including:
    - fainting
    - shortness of breath
    - skin reactions

- Instructions for omission of one or more doses:

If you forget to take MEFSAL

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 product, ask your doctor or pharmacist.

V. POSSIBLE SIDE EFFECTS.

Description of side effects

Like all medicines, MEFSAL 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 severe (Stevens-Johnson Syndrome and toxic epidermal necrolysis), lesions of soft tissues (mucosal lesions) or 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.
- 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 Uaundice)
    - 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 certain non-steroidal anti-inflammatory drugs (NSAIDs) may be accompanied, in particular with high doses and in the case of long-term treatment, with a slightly increased risk of occlusion of the arterial vessels (arterial thrombotic events), Which can cause a heart attack (myocardial infarction) or stroke (apoplexy).
Retention of fluids (edema), increased blood pressure (hypertension) and heart failure were observed in combination with NSAID therapy.
The most commonly observed adverse reactions affect the digestive system (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 (maleana)
- vomiting of blood (haematemesis)
- inflammation with building of ulcers in the mouth (ulcerative stomatitis)
- worsening of inflammation of the large bowels (exacerbation of colitis)
- worsening of inflammation of the digestive tract (exacerbation of Crohn’s disease).

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

Side effects of meloxicam - the active substance of MEFSAL

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

Common (may affect 1 to 10 in 100 people):
- headache

Uncommon (may affect 1 to 10 in 1000 people):
- dizziness (light-headedness)
- a feeling of dizziness or spinning (vertigo)
- somnolence (drowsiness)
- anaemia (reduction of the concentration ofthe 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 (arrhythmias)
  - 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 (angioneuroticoedema)
- 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 1 to 10 in 10000 people):
- mood disorders,
- nightmares,
- abnormal blood count, including:
  - abnormal differential blood count,
  - decrease in the number of white blood cells (leukocytopenia),
  - reduction in the number of blood platelets (thrombocytopenia),
    These side effects can increase the risk of infections, as well as symptoms such as bruising or nose bleeds.
- ringing in the ears (tinnitus),
- palpitations,
- ulcers of the stomach or upper part of the small intestine (peptic / gastroduodenal ulcers),
- inflammation of the gullet (esophagitis),
- asthma attacks (seen in people who are allergic to aspirin or other NSAIDs),

- severe skin reactions with blisters or skin detachment (Stevens-Johnson Syndrome and Lyell's Syndrome),
- nettle rash (urticaria),
- vision abnormalities, including:
  - blurred vision
  - conjunctivitis (inflammation of the eyeball or eyelids)
- inflammation of the large intestine (colitis)

Very rare (may affect less than 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 lead to the following symptoms:
  - yellowing of the skin or eyeballs (jaundice),
  - abdominal pain,
  - loss of appetite,
- acute functional renal failure in particular in patients with risk factors such as heart disease, diabetes or kidney disease,
- Perforation of the intestinal wall.

Not known (frequency cannot be estimated from the available data):
- confusion
- disorientation
- shortness of breath and skin reactions (anaphylactic / anaphylactoid reactions),
- skin rashes caused by exposure to sunlight (photosensitivity reactions),
- heart failure has been reported in association with NSAID therapy,
- complete loss of specific types of white blood cells (agranulocytosis), especially in patients who take MEFSAL 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
  - infection

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

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)

If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

VI. STORAGE CONDITIONS

Store in the original package in order to protect from moisture.
Prescription only medicine (POM)
Keep out of the reach and sight of children.
Do not use after the expiry date which is stated on the carton
If necessary, warnings against visible signs of deterioration

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

VII. DATE OF REVISION OF THE LEAFLET:

July 2015

This is a medicine. A drug is not a product like any other. It concerns you, you and your health. The drug is an active product. A long search made it possible to discover its activity.
But its absorption is not always safe, Never abuse drugs. Only use medication properly.
Use prescribed medications as your doctor tells you. He knows what medications you need. Execute exactly the prescriptions of his prescription: follow the prescribed treatment, do not interrupt it, Do not take it back on your own initiative. Your pharmacist knows the medications / follow his advice.
It is not for you to take a lot of medication. This is for you to take the medications you need.

Manufactured By:
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