

Mefac[®] Hard Capsules

250 mg

LM 100Lb18a 01-11
ET92

Mefenamic Acid



100 Hard Capsules

PA Holder:
ROWA[®]
Pharmaceuticals Ltd.
Bantry, Co. Cork, Ireland
PA 74/15/1

Marketed by:
ROWEX[®]
Bantry, Co. Cork, Ireland

COMPOSITION:

Each hard capsule contains:
Mefenamic Acid 250 mg.
Excipients include: Lactose
monohydrate. See leaflet for
further information.

DOSAGE:

For oral use as directed by the
Physician. Do not exceed the stated
dose. Capsules should be taken
preferably with food.

Do not store above 25°C. Keep out
of the reach and sight of children.

PACKAGE LEAFLET: INFORMATION FOR THE USER

Mefac 250mg Hard Capsules

Mefenamic Acid

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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Mefac is and what it is used for
2. Before you take Mefac
3. How to take Mefac
4. Possible side effects
5. How to store Mefac
6. Further information

1. What Mefac is and what it is used for

Mefac contains an active substance called Mefenamic Acid. This belongs to the group of medicines called NSAIDs (non-steroidal anti-inflammatory drugs). Mefac is used for the relief of mild to moderate pain and inflammation associated with rheumatic, muscular or arthritic disorders, trauma, headache, dental pain, pain following surgery or childbirth and also for relief of period pains.

2. Before you take Mefac

Do not take Mefac if you:

- Are allergic (hypersensitive) to mefenamic acid or any of the other ingredients of Mefac (See section 6: Further information)
- Are allergic to aspirin (acetylsalicylic acid), ibuprofen or other NSAIDs
- Are pregnant or breast-feeding
- Suffer from kidney or liver impairment or heart failure
- Are taking another medicine known as a cyclooxygenase-2 inhibitor
- Have ever had peptic ulceration (ulcer in the stomach or duodenum) or bleeding in the digestive tract or inflammatory bowel disease

Take special care with Mefac

- Discontinue at first sign of skin rash, lesions, or signs of hypersensitivity.
- If you are elderly and/or taking Mefac for a long time, you should visit

your doctor regularly to monitor adverse events as the elderly are more prone to adverse events.

- Mefac 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.
- Medicines such as Mefac 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.
- If you have heart problems, previous stroke or think that you might be at risk of these conditions (e.g. if you have high blood pressure, diabetes or high cholesterol or are a smoker), you should discuss your treatment with your doctor or pharmacist.
- If you are dehydrated, have or had asthma, high blood pressure, heart failure, systemic lupus erythematosus, (a connective tissue

disorder), epilepsy, a bleed in your brain or a tendency to bleed easily.

- If you notice any signs of bleeding or side effects, which affect the stomach or intestine, or signs of a skin rash or blistering of the skin, inform your doctor immediately.
- If the capsules cause any of the side effects listed, it may be necessary to stop taking them.

Use of painkillers for headaches over a long time may make them worse. If this occurs contact your doctor.

Stomach ulcers, perforation or stomach and/or intestinal bleeding, sometimes fatal, have been reported for NSAIDs (the group of medicines to which Mefac belongs). Smoking and drinking alcohol are added risk factors.

The risk of stomach ulcers, perforation or stomach and/or intestinal bleeding increases with higher doses, in patients with a history of ulcers and in the elderly. If any of these apply to you, your treatment should be started at the lowest available dose. Your doctor may also ask you to take a medicine that reduces the risk of developing ulcers (e.g. misoprostol and proton pump inhibitors). If you require a low dose aspirin or other drugs which may increase the risk to your stomach (see 'Taking other medicines') you may also be asked to take a medicine to reduce the risk of developing ulcers.

If you have a history of stomach and/or intestinal toxicity, especially if you are elderly, you should report any stomach symptoms, especially stomach and/or intestinal bleeding.

If stomach and/or intestinal bleeding or ulceration occurs your treatment should be withdrawn.

If you are taking Mefac for a long time you should be regularly monitored by your doctor, paying particular attention to development of diarrhoea, rash, liver dysfunction and abnormal condition of the blood. Treatment should be stopped immediately if any of these conditions appear.

Taking 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. This includes herbal medicines. This is because Mefac can affect the way some medicines work. Also some other medicines can affect the way Mefac works.

Tell your doctor or pharmacist if you are taking any of the following:

- Steroid drugs
- Anti-platelet agents (to prevent blood cells sticking together)
- Anti-coagulants (to prevent clots) such as warfarin or heparin as the doctor may wish to make more frequent checks on your blood clotting.
- Medicines used to treat anxiety and depression known as Serotonin Selective Re-uptake Inhibitors (SSRIs) such as fluoxetine
- certain types of antibiotics called quinolones or aminoglycosides
- medicines for high blood pressure (anti-hypertensives)
- diuretics (used to treat excess fluid in the blood)
- medicines for depression (lithium, anti-depressants)
- medicines for heart problems (cardiac glycosides, warfarin, aspirin)
- medicine for gout (probenecid)
- medicines for diabetes (hypoglycaemic agents)

- medicines to prevent graft rejection (cyclosporin, tacrolimus)
- medicines to treat leukaemia (methotrexate)
- medicines used for the termination of pregnancy (mifepristone)

If you are not sure if any the above applies to you, talk to your doctor or pharmacist before taking Mefac.

Pregnancy and breast-feeding

This product should not be taken during pregnancy and lactation.

Ask your doctor or pharmacist for advice before taking any medicine

Driving and using machines

This medicine may cause drowsiness, dizziness and impaired vision.

If you are affected you should not drive or operate machinery.

Important information about some of the ingredients of Mefac

Mefac contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

3. How to take Mefac

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

Mefac is for oral use.

The capsules should be taken with a glass of water, with or after meals.

Adults only:

The usual daily dose is 2 capsules taken 3 times a day.

Children (under 12 years):

Mefac is not recommended for children.

Elderly:

Caution should be used in elderly patients as they are more prone to the side effects of Mefac.

If you take more Mefac than you should

If you take more Mefac than you should, talk to your doctor or go to a hospital straight away. Take the medicine pack with you. The following effects may happen: acute renal failure and coma.

If you forget to take Mefac

Skip the missed dose.

Take the next dose as usual.

Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Mefac can cause side effects, although not everyone gets them.

The most commonly observed adverse events affect the stomach and intestine. Stomach ulcers perforation or stomach and/or intestinal bleeding, sometimes fatal, particularly in the elderly may occur.

Common (affects less than 1 out of 10 people)

Diarrhoea

If you suffer from diarrhoea during your treatment, stop taking the medicine and contact your doctor.

The following side-effects frequency are not known (cannot be estimated from the available data)

Gastrointestinal: Stomach pain, feeling sick, flatulence, constipation, heartburn, passing black tarry stools, vomiting blood, mouth ulcers, loss of appetite, inflammation of large and small intestine, Crohn's disease, inflammation of the pancreas and stomach ulcer

Kidney: Kidney disorders including painful urination, difficulty passing urine, blood in the urine, protein in the urine, kidney failure.

Blood: Anaemia, reduction in certain types of blood cells including

lowering of white blood cells (**rare**), which increases the risk of infection, low sodium levels in blood.

Neurological: Disturbance of vision, reversible loss of colour vision, eye irritation, sensations of prickling or burning, inflammation of the tissues that cover the brain or spinal cord particularly in patients with Systemic Lupus Erythematosus (disease of the immune system) or a mixed connective tissue disorder (with symptoms such as a stiff neck, headache, feeling sick, vomiting, fever and disorientation), depression, confusion, hallucinations, ringing in the ear, ear pain, vertigo, malaise (feeling of being unwell), fatigue, drowsiness, convulsions (fits), dizziness, difficulty in sleeping and headache.

Cardiovascular: Palpitations, drop in blood pressure, swelling of feet, ankles or legs, high blood pressure. Medicines like Mefac (especially in long-term use) have been associated with a small increase in the risk of

heart attack or stroke.

Skin: a serious skin reaction such as rash, blistering or peeling of the skin or mucous membrane (erythema multiforme, Lyell's syndrome (toxic epidermal necrolysis), Stevens-Johnson syndrome), sweating, rash, sensitivity to light, hives, swelling of the lips, face, tongue or larynx.

Other: Nervousness, elevation of liver function test and other liver disorders, allergic reactions, asthma, uncomfortable breathing following exercise, changes in blood sugar control in diabetic patients, fever, yellowing of the skin.

This type of medicine can occasionally cause allergic reactions. Tell your doctor straight away if you experience any of the following symptoms of a serious allergic reaction: anaphylaxis (a life-threatening reaction including shock and collapse) wheezing and feeling of tightness in the

chest, uncomfortable breathing, swelling of the face, lips, mouth, tongue or throat, blistering or peeling of the skin or mucous membrane.

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

5. How to store Mefac

Keep out of the reach and sight of children.

Do not use Mefac after the expiry date which is stated on the label of the container after EXP. The expiry date refers to the last day of that month. Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Mefac contains

- The active substance is mefenamic acid (250 mg).

- The other ingredients are dried maize starch, purified talc, lactose monohydrate and sodium laurilsulfate. The capsules are comprised of gelatin, titanium dioxide (E171), erythrosin (E127) and patent blue V (E131) while the printing ink opacode grey contains shellac glaze, titanium dioxide (E171), black iron oxide (E172), propylene glycol (E1520) or tekprint grey ink which contains shellac, propylene glycol (E1520), strong ammonia solution, potassium hydroxide, titanium dioxide (E171) and black iron oxide (E172).

What Mefac looks like and contents of the pack

Mefac are size 1, opaque, hard gelatin capsules with a white body and a blue cap. Both the cap and the body have the word 'MEFAC 250' printed in grey and contain a white powder.

The capsules are available in white polypropylene containers of 50, 100 and 500 capsules. Not all pack size may be marketed.

Marketing Authorisation Holder: Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland

Manufacturers: Dales Pharmaceuticals Ltd., Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, UK.
Rowa Pharmaceuticals Ltd., Bantry, Co Cork, Ireland.

Marketed by: Rowex Ltd., Bantry, Co Cork, Ireland.

This leaflet was last approved in January 2011.