

Mefac 500mg Film-coated Tablets

Mefenamic acid

100 Film-coated Tablets

PA Holder:

Rowa Pharmaceuticals Ltd., Bantry Co. Cork, Ireland

PA 74/15/2

Marketed by:

Rowex Ltd., Bantry, Co. Cork, Ireland

COMPOSITION:

Each film-coated tablet contains 500mg mefenamic acid. Also includes sunset yellow E110. See leaflet for further information.

DOSAGE:

As directed by the Physician. Do not exceed the stated dose. Tablets should be taken preferably with or after food.

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

Package leaflet: Information for the user

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

What is in this leaflet

1. What Mefac is and what it is used for
2. What you need to know before you take Mefac
3. How to take Mefac
4. Possible side effects
5. How to store Mefac
6. Contents of the pack and other 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. Mefac is also used for relief of period pains, management of excessively heavy periods and symptoms of premenstrual syndrome (PMS).

2. What you need to know before you take Mefac

Do not take Mefac if you

- are allergic to mefenamic acid or any of the other ingredients of this medicine (listed in section 6)
- are allergic to aspirin (acetylsalicylic acid), ibuprofen or other NSAIDs
- are pregnant or breastfeeding
- suffer from kidney or liver impairment or heart failure
- are seeking pain relief after heart bypass surgery
- are taking another medicine known as a cyclooxygenase-2-inhibitor
- have ever had a peptic ulceration (ulcer in the stomach or duodenum) or bleeding in the digestive tract or inflammatory bowel disease.
- are a child under 12 years of age

Warnings and precautions

Talk to your doctor or pharmacist before taking 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 effects as the elderly are more prone to adverse events.
- if you are trying to become pregnant (see section on fertility).
- 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, discuss with your doctor or pharmacist.
- 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 tablets 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 of 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 of 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 'Other medicines and Mefac') 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.

Other medicines and Mefac

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 (cyclosporine, tacrolimus)
- medicines to treat leukaemia (methotrexate)
- a medicine usually prescribed through hospitals, called mifepristone (taken within the last 12 days)
- anti-viral medicine (zidovudine)

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

Pregnancy and breastfeeding

Pregnancy: Mefenamic acid may be passed to your unborn baby. DO NOT take these tablets if you are pregnant or planning to become pregnant unless advised by your doctor.

Breast-feeding: Mefenamic acid passes into breast milk and can affect the baby. You should not take the tablets while breast-feeding unless advised by your doctor.

Fertility: DO NOT take the tablets if you are trying to become pregnant as they may make it more difficult to get pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

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.

Mefac contains sunset yellow (E110). Sunset yellow (E110) may cause allergic reactions.

3. How to take Mefac

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

Mefac is for oral use. The tablets should be taken whole with a glass of water, with or after meals.

Adults only: The usual daily dose is 1 tablet taken 3 times a day.

Children (under 12 years): Mefac is not recommended.

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

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 affects 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, this medicine can cause side effects, although not everybody gets them.

STOP taking the tablets and seek medical help immediately 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.
- 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)
- diarrhoea, passing black tarry stools or vomiting blood

Tell your doctor if you get any of the following side effects:

Not known: frequency cannot be estimated from the available data
Gastrointestinal: Stomach pain, feeling sick, flatulence, constipation, heartburn, mouth ulcers, loss of appetite, inflammation of large and small intestine, Crohn's disease, inflammation of the pancreas, 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, sensation 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 convulsion (fits), dizziness, difficulty in sleeping and headache.

Cardiovascular: Palpitation, 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: 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.

Reporting of side effects

If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mefac

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

Store in the original package. Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. Do not store above 25°C.

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 Mefac contains

- The active substance is mefenamic acid. Each tablet contains 500mg mefenamic acid.
- The other excipients are microcrystalline cellulose, povidone, sodium starch glycollate Type A, magnesium stearate, hypromellose (E464), titanium dioxide (E171), quinoline yellow (E104), sunset yellow (E110) and indigo carmine (E132).

What Mefac looks like and contents of the pack

Mefac are yellow, oval, film-coated tablets.

Mefac is available in white containers containing 100 tablets.

Marketing Authorisation Holder/Manufacturer:

Rowa[®] Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland

This leaflet was last revised in June 2015.