1. WHAT ARE MEFENAMIC ACID CAPSULES AND WHAT ARE THEY USED FOR

Mefenamic Acid Capsules belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines reduce pain and inflammation, and bring down a high temperature.

Mefenamic Acid Capsules are most commonly used for relief of mild to moderate pain including muscle pains and pain after injury, headaches and toothaches, period pains and pain following an operation or after childbirth, pain due to rheumatoid arthritis and osteoarthrosis. It is also used to treat excessively heavy periods caused by abnormal function and presence of a contraceptive coil, where the disease in the pelvis has been ruled out.

2. BEFORE YOU TAKE MEFENAMIC ACID CAPSULES

DO NOT take Mefenamic Acid Capsules if:

• You know that you are allergic to Mefenamic Acid or any of the other ingredients in these Capsules (listed at the end of this leaflet)
• You currently have a stomach ulcer or bleeding
• You have suffered from stomach ulcers or bleeding two or more times in the past
• You suffer from inflammatory bowel disease
• You show any signs of allergy (such as asthma, hay fever or skin rash) to aspirin, ibuprofen or other NSAIDs. An allergic reaction may include swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
• You have severe problems with your kidneys or liver
• You suffer from severe heart failure
• You had a major heart surgery
• You are in the last three months of pregnancy
• You are breast feeding.

Take special care with Mefenamic Acid Capsules and check with your doctor or pharmacist before taking your medicine if:

• You have had an ulcer or some other problem affecting your stomach, or intestines
• You have asthma or wheezing attacks (or if you have had asthma in the past)
• You have any heart, liver or kidney problems
• You are elderly
• You suffer from epilepsy (fits)
• You suffer from any abnormality of the blood
• You are dehydrated (for example you have been losing fluid through vomiting, diarrhoea or passing too much or too little, urine (fluids)
• You have frequent headaches
• You drink alcohol
• You have a connective tissue disorder e.g. Systemic Lupus Erythematosus (SLE) resulting in joint pain, skin change and disorders of other organs

• You have a problem with the metabolism of sugar in your body
• You are trying to get pregnant (see section on pregnancy).
If you are having a medical examination, tell the doctor that you are taking Mefenamic Acid Capsules as they reduce the signs of fever and inflammation which would otherwise be noticed.

Medicines such as Mefenamic Acid Capsules may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke. Any risk is more likely with higher doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems or suffered from a previous stroke or think that you may be at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or recently have taken any other medicines, including medicines obtained without a prescription.

Mefenamic Acid Capsules may affect or be affected by the following medicines:

• Anticoagulants (drugs used to thin the blood to prevent blood clots, e.g. warfarin, heparin)
• Antiplatelet tablets (to prevent blood clots, e.g. clopidogrel)
• Antihypertensives (for the treatment of high blood pressure)
• Lithium (for depression)
• Medicines for the treatment of heart conditions (e.g. digoxin)
• Quinolone antibiotics (for an infection e.g. ciprofloxacin, norfloxacin and nalidixic acid)
• Any other NSAID (for painful or inflammatory conditions e.g. aspirin, COX-2 selective inhibitors like valdecoxib, parecoxib and refocoxib, ibuprofen)
• Milfepristone (used to terminate pregnancies)
• Methotrexate (which can be used to treat certain tumours and other diseases including psoriasis and rheumatoid arthritis)
• Ciclosporin or tacrolimus (used to suppress the body’s immune system, e.g. following transplants or in diseases such as psoriasis and rheumatoid arthritis)
• Corticosteroids (used for the treatment of asthma and various inflammatory conditions e.g. beclomethasone)
• Probenecid used in treatment of swollen joints
• Drugs used in diabetes (e.g. glibenclamide)
• Drug used as antibiotics (e.g. Gentamicin, Neomycin, Kanamycin)
• Zidovudine (an anti-viral drug)
• SSRIs such as fluoxetine or sertaline (for depression).

Pregnancy and breast feeding

Ask your doctor or pharmacist for advice before taking any medicine. Mefenamic Acid Capsules may make it difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant. Mefenamic Acid Capsules should, if possible not be taken during pregnancy. You should not take Mefenamic acid capsules if you are in the last three months of pregnancy or if you are breast feeding, speak to your doctor or pharmacist before taking these capsules. Mefenamic acid should not be given to the mother and the neonate, at the end of pregnancy, as there is a possibility of possible prolongation of bleeding time. During delivery, it may inhibit contractions of uterus resulting in delayed or prolonged delivery.

Driving and using machines

NSAIDs may sometimes cause symptoms such as drowsiness, dizziness, weakness and visual disturbances. If you notice any such
Important information about some of the ingredients of Mefenamic Acid Capsules
This medicine also contains lactose. If you have been told by your pharmacist for advice.

Symptoms, do not drive or operate machinery and ask your doctor or pharmacist for advice.

3. HOW TO TAKE MEFENAMIC ACID CAPSULES

Make sure you take your Capsules exactly as directed by your doctor.
The instructions will be written on the label. You should check with
your doctor or pharmacist if you are not sure.

Mefenamic Acid Capsules should be taken with or after food.
The capsules should be swallowed whole with water. Do not chew
them or break them.

Adults: The usual dose is two Capsules three times each day.
For excessively heavy periods, start taking your medicine on the first
day of excessive bleeding and continue as directed by your doctor.
For period pains, start taking your medicine when you first notice the
pain and continue as directed by your doctor.
As a general principle, the smallest effective dose should be used.

Elderly: The adult dose can be used, although these Capsules should
be used with caution in patients suffering from dehydration or kidney
failure.

Children: Mefenamic Acid Capsules are not recommended for use in
children.
If you have a history of ulcers or some other problem affecting your
stomach or intestines, you should inform your doctor or pharmacist if you
notice any unusual symptoms affecting your abdomen (stomach)
especially blood in your stomach, urine or stool, particularly if these
symptoms occur during the initial phase of your treatment.

If you take more Mefenamic Acid Capsules than you should:
If you (or someone else) take too many of these capsules, you may
experience headache, nausea, vomiting, pain in abdomen, blood in
stool or vomiting, diarrhoea, disinclination, excitement, coma,
drowsiness, dizziness, ringing in ear, fainting, occasionally
convulsions. In cases of significant poisoning acute kidney failure and
salt levels in the body
• Symptoms such as sleep disturbance, depression, confusion,
nervousness, hallucinations (imagining sensations), noise in the
ears or impaired hearing, vertigo, dizziness, tingling or other odd
sensations, problems with your eyesight or drowsiness have
occasionally been reported.

• Symptoms of aseptic meningitis such as, over-reaction of the skin to
sunlight, persistent headache, a stiff neck, fever, drowsiness or
muscle pain may occur in some patients (especially in patients with
existing auto immune disorders, such as systemic lupus
erythematous, mixed connective tissue disease)

• Medicines such as mefenamic acid 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. Do not
exceed the recommended dose or duration of treatment. If you have
heart problems, previous stroke or think that you might be at risk of
these conditions (for example if you have high blood pressure,
diabetes or high cholesterol or are a smoker) you should discuss
your treatment with your doctor or pharmacist.

Your doctor may try to minimise any undesirable effect by giving you
the lowest effective dose of Mefenamic Acid Capsules for the shortest
amount of time necessary to control your symptoms.

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 MEFENAMIC ACID CAPSULES

Keep out of the reach and sight of children.
Do not use Mefenamic Acid Capsules after the expiry date which is
stated on the label. They should be stored in a cool, dry place, below
25°C. Keep in original container to protect from light.

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.

Remember:
This medicine is for you. Only a doctor can prescribe it for you. Never
give this medicine to someone else, it could harm them, even if their
symptoms seem the same as yours.

6. FURTHER INFORMATION

What Mefenamic Acid Capsules contain
Each Mefenamic Acid Capsule contains 250mg of the active
substance, mefenamic acid.
The other ingredients are maize starch, lactose, purified water,
magnesium stearate, sodium starch glycollate, sodium lauryl sulphate.

What Mefenamic Acid Capsules look like and contents of the pack
Mefenamic Acid Capsules are hard gelatin capsules with a blue cap
and yellow body. They are packed in polypropylene securitainers with
child proof lids (50, 84, 100, 168 and 500 capsules).

Marketing Authorisation Holder and Manufacturer:
Mercury Pharmaceuticals Ltd
No. 1 Croydon, 12-16 Addiscombe Road, Croydon CR0 0XT, UK.
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