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

In this leaflet:
1. What mefenamic acid is and what it is used for
2. What you need to know before you take mefenamic acid
3. How to take mefenamic acid
4. Possible side effects
5. How to store mefenamic acid
6. Contents of the pack and other information

1. What mefenamic acid is and what it is used for
Mefenamic acid is one of a group of medicines called non-steroidal anti-inflammatory drug. It causes a reduction in the levels of prostaglandins, substances believed to be responsible for causing pain and inflammation, and bring down a high temperature.

Mefenamic acid is used for the relief of pain and discomfort caused by arthritis, muscular pain, headache, periods, toothache, and fever in children. It may also be used to relieve pain after operations or childbirth, pain due to rheumatoid arthritis and osteoarthritis. 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. What you need to know before you take mefenamic acid

Do not take mefenamic acid capsules if you:
- are allergic to mefenamic acid or any other ingredients of this capsule (listed in section 6)
- had an allergic reaction after taking mefenamic acid, aspirin or any other medicine used to treat painful conditions. An allergic reaction may include skin rash, asthma, itchy or runny nose, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- have or have ever had peptic ulceration (ulcer in your stomach or duodenum) or bleeding in your digestive tract
- are in the last three months of pregnancy
- have severe problems with your liver, kidney or heart
- had a major heart surgery
- suffer from inflammatory bowel disease
- have ever had stomach pains, felt like being sick or had heartburn after taking aspirin or any other medicine used to treat painful conditions

Warnings and precautions
Talk to your doctor or pharmacist before taking these capsules if you:
- have asthma or wheezing attacks (or if you have had asthma in the past)
- have high blood pressure
- have any other heart, liver or kidney problems
- are elderly
- suffer from epilepsy (fits)
- suffer from any abnormality of the blood
- are dehydrated (for example you have been losing fluid through vomiting, diarrhoea or passing too much or too little, urine (fluids))
- have frequent headaches
- drink alcohol
- have a connective tissue disorder eg Systemic Lupus Erythematosus (SLE) resulting in joint pain, skin change and disorders of other organs
- have a problem with the metabolism of sugar in your body
- 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
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because mefenamic acid can affect the way some other medicines work, also some other medicines may change the way mefenamic acid works.

In particular, tell your doctor if you are taking:
- other non-steroidal anti-inflammatory drugs (eg ibuprofen)
- anti-platelet tablets (to prevent blood clots, eg clopidogrel)
- medicines used to thin the blood (anticoagulants, eg warfarin)
- diuretics (water tablets) and other drugs used to treat high blood pressure (eg furosemide and Indapamide)
- medicines used for heart trouble (eg digoxin)
- lithium, a treatment for depression
- methotrexate, a drug used in cancer therapy
- ciclosporin, a drug used following organ transplants
- quinoline antibiotics, which are used to treat bacterial infections (eg ciprofloxacin)
- mifepristone, a drug used for terminating pregnancy
- corticosteroids, which are used to treat allergic and inflammatory diseases and immune reactions (eg prednisolone)
- probenecid used in treatment of swollen joints
- drugs used in diabetes (eg glibenclamide)
- drug used as antibiotics eg gentamycin, neomycin, kanamycin)
- zidovudine (an anti-viral drug)
- SSRIs such as fluoxetine or sertraline (for depression)

If you are not sure, talk to your doctor or pharmacist before taking mefenamic acid.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine. Mefenamic acid capsules 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.

Mefenamic acid Capsules should, if possible not be taken during pregnancy.
It is possible that you may be able to take mefenamic acid Capsules whilst you are breast feeding but you should speak to your doctor or pharmacist before taking these capsules.

Driving and using machines
NSAIDs may sometimes cause symptoms such as you feel dizzy or drowsy, weakness and visual disturbances. If you notice any such symptoms, you should not drive or operate machinery until you know how the drug affects you, and ask your doctor or pharmacist for advice.

Mefenamic acid Capsule contains lactose
This medicine also 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.

Tests
Mefenamic acid can reduce the number of certain types of blood cells, and therefore your doctor may wish to perform regular blood tests while you are taking this medicine.
If you have a blood test for any other reason, remember to tell the doctor that you are taking mefenamic acid.

If you have a urine test, tell the doctor that you are taking mefenamic acid because the medicine may affect the result.

3. How to take mefenamic acid

Always take this medicine exactly as your doctor has told you. The pharmacist’s label should tell you how much to take and how often. If it does not or you are not sure ask your doctor or pharmacist. The capsules should be swallowed with a drink of water. To be taken preferably with or after food. Do not chew them or break them.

**Dosage**

Adults: The usual dose is 2 capsules taken three times daily.

Dysmenorrhoea (painful periods): Begin taking this medicine at the onset of period pain. Your doctor will advise you how long you should take this medicine for.

Menorrhagia (heavy or prolonged periods): Begin taking this medicine on the first day of excessive bleeding. Your doctor will advise you how long you should take this medicine for.

**Elderly:** Your doctor will put you on the lowest effective dose, to minimise side effects. The adult dose can be used; although these capsules should be used with caution in patients suffering from dehydration or kidney failure. You should be under regular supervision by your doctor while taking this medicine.

**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 capsules than you should

If you or a child accidentally takes too many Capsules, contact your nearest hospital casualty department or doctor immediately. Bring the container with any remaining capsules with you.

Signs of an overdose include headache, nausea, vomiting, pain in abdomen, blood in stool or vomiting, diarrhoea, disorientation, excitement, coma, drowsiness, dizziness, ringing in ear, fainting, occasionally convulsions. In cases of significant poisoning acute kidney failure and liver damage are possible.

If you forget to take a dose

If you forget to take a dose, take it as soon as you remember, unless it is nearly time to take the next one. Never take two doses together and then go on as before.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

STOP taking the capsules and seek medical help immediately if you have any of the following allergic reactions:

- sudden wheeziness, difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin (especially affecting your whole body), with a red rash or raised lumps
- blisters of the mouth, eyes, and genital region, and patchy areas of rash, peeling skin or any of the following reactions:
  - passing blood in your stools (faeces/motions)
  - passing black tarry stools
  - pass loose stool (Diarrhoea)
  - vomiting any blood or dark particles that look like coffee grounds
- indigestion or heartburn
- abdominal pain (pains in your stomach) or other abnormal stomach symptoms
- persistent sore throat or high temperature
- yellowing of your skin or the whites of your eyes

Other Side Effects

You should tell your doctor as soon as possible if you notice any of the following side effects after taking this medicine:

- blurred vision, pain in the eyes
- sore mouth, and/or lips, puffiness of the face
- hallucinations, anaemia, red urine
- your skin may become more sensitive to light
- bruising or bleeding easily
- protein in the urine (your doctor may test for this from time to time)
- change in your urine output or appearance, possibly accompanied by kidney pain

The following side effects are often mild and may wear off after a few days’ treatment. If they are severe or last more than a few days, tell your doctor.

- stomach discomfort, nausea (feeling sick), vomiting
- headaches, a ringing in the ears
- feeling unwell, pins and needles

Other rare side effects include confusion, depression, dizziness, drowsiness, vertigo (spinning sensation) and severe skin disorders.

Medicines such as mefenamic acid may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke (see section 2 - Warnings and precautions).

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store mefenamic acid

Keep all medicines out of the sight and reach of children

- Do not use the Capsules after the expiry date stated on the label after ‘EXP’. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Keep container tightly closed.
- Store in original container.

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 mefenamic Acid Contains**

Mefenamic acid 250mg Capsules:

- The active substance is mefenamic Acid. Each capsule contains 250mg of mefenamic acid.
- The other ingredients are lactose monohydrate, gelatine, sodium starch glycollate and sodium lauryl sulphate. The capsule shell contains gelatine and the colours patent blue (E131), erithrosine (E127), yellow iron oxide (E172) and titanium dioxide (E171). Each capsule contains 450 micrograms of sodium.

See end of section 2 for further information on lactose.

What mefenamic acid looks like and what is the pack

- Mefenamic acid 250mg Capsules are blue and brown in colour and printed with PV and M250 mg.
- Mefenamic acid 250mg Capsules are available in packs containing 50, 84, 100, 250, 500 and 1000 capsules. Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer:

Pharmvit Ltd, 177 Bilton Road, Perivale, Greenford, Middlesex UB6 7HQ.

Telephone: 0208 997 5444

Fax: 0208 997 5433

To request a copy of this leaflet in large print or audio format or additional copies, please contact the licence holder at the address (or telephone, fax) above.

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