

## **Package leaflet: Information for the user**

### **Mefenamic Acid 500 mg film-coated Tablets**

#### **Mefenamic Acid**

**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 Mefenamic Acid Tablets are and what they are used for
2. What you need to know before you take Mefenamic Acid Tablets
3. How to take Mefenamic Acid Tablets
4. Possible side effects
5. How to store Mefenamic Acid Tablets
6. Contents of the pack and other information

#### **1. What Mefenamic Acid Tablets are and what they are used for**

Mefenamic Acid Tablets contain the active substance mefenamic acid. Mefenamic acid belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Mefenamic Acid Tablets are used to treat the following:

- Symptoms of pain or swelling associated with arthritis, rheumatoid or muscular disorders.
- Pain associated with trauma or surgery.
- Muscle or dental pain, headaches.
- Pain after childbirth.
- Period pain or abnormally heavy periods.

#### **2. What you need to know before you take Mefenamic Acid Tablets**

##### **Do not take Mefenamic Acid Tablets:**

- if you are allergic (hypersensitive) to mefenamic acid or any of the other ingredients of this medicine (listed in section 6 “Contents of the pack and other information”);
- if you are allergic to any other NSAIDs such as aspirin, ibuprofen or celecoxib;
- if you have an inflammatory bowel disease such as Crohn’s disease or ulcerative colitis;
- if you have a history of gastrointestinal conditions such as bleeding in the stomach, peptic ulcer, gastritis;
- if you have severe heart, liver or kidney failure;

- if you are in the last trimester of pregnancy (more than 6 months pregnant);
- if you have had heart bypass surgery.

### **Warnings and precautions**

#### **Talk to your doctor or pharmacist before taking Mefenamic Acid Tablets if:**

- you are taking any other NSAIDs such as ibuprofen, diclofenac;
- you are taking any other anti-inflammatory medicines, including steroids such as prednisolone;
- you are taking medicines such as warfarin or clopidogrel, which are used to thin the blood;
- you are taking selective serotonin medicines such as paroxetine, which are antidepressants;
- you have liver or kidney problems, as your doctor may monitor their function before and during treatment;
- you are trying to become pregnant (see section “Fertility”);
- you are elderly (see section 3 “How to take Mefenamic Acid Tablets”);
- previously taking painkillers such as aspirin have given you an upset stomach, or you have a history of stomach or digestive tract problems. Patients taking mefenamic acid can experience bleeding in the stomach or gut;
- you are going to have a major operation or have a bleeding disorder, as mefenamic acid can affect how your blood clots (it can make you bleed more or for longer periods of time);
- you have or have a history of asthma, as it may cause difficulties in breathing;
- you have epilepsy;
- you have a disorder of the connective tissue, such as Systemic Lupus Erythematosus (SLE);
- you are dehydrated with symptoms of thirst, dry mouth, dry skin, dark urine, headache;
- you have problems with your heart, have previously had a stroke, or you think you may be at risk of these conditions (e.g. if you have diabetes, high blood pressure, are a smoker, or have high cholesterol). Your doctor may carry out additional monitoring.

Medicines such as Mefenamic Acid Tablets may be associated with a small increased risk of stroke or heart attack. Any such risk is more associated with high doses, and prolonged treatment.

**Do not exceed** the recommended dose or treatment duration.

### **Other medicines and Mefenamic Acid Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes any herbal medicines and medicines obtained without a prescription.

Mefenamic Acid Tablets may affect other medicines and other medicines, in turn, may affect how well Mefenamic Acid Tablets work.

Tell your doctor or pharmacist if you are taking:

- medicines which can increase the chances of bleeding in the stomach or gut, or increase the risk of getting ulcers such as:
  - medicines used to treat arthritis and inflammation (corticosteroids);
  - medicines used to thin the blood (anti-platelet drugs such as warfarin, aspirin, clopidogrel);
  - anti-depressant medicines such as paroxetine, which are selective serotonin re-uptake inhibitors (SSRIs);
  - medicines which are anti-inflammatory, such as diclofenac, celecoxib;
- aspirin, used in some heart conditions to stop your blood from clotting;
- medicines used to treat high blood pressure, such as atenolol, ramipril, valsartan;
- water tablets (diuretics), or medicines for the heart, such as digoxin, diltiazem, sotalol;
- medicines used to treat diabetes, such as glibenclamide, glipizide;
- medicines used to suppress the immune system, such as ciclosporin, methotrexate, tacrolimus;
- medicines used to treat some types of depression, and mood swings, such as lithium;
- a medicine called mifepristone which has been taken within the last 12 days. This is usually prescribed via hospitals;
- quinolone or aminoglycoside antibiotics, used to treat infections;
- zidovudine, used for HIV;
- probenecid, used in special situations to protect the kidneys;
- medicines which bind to protein in the blood (check with your pharmacist).

### ***Blood tests***

During treatment, your doctor may test your blood.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

### **Pregnancy**

Mefenamic acid passes to your unborn baby. During the first six months of pregnancy, it is not known how mefenamic acid can affect your unborn baby. Your doctor or pharmacist will help you decide whether or not to take these tablets in the first six months of pregnancy.

Mefenamic Acid Tablets should not be taken in the last three months of pregnancy, as this may prolong its duration and delay the onset of labour. This could also lead to bleeding in the mother or unborn baby.

**Breast-feeding**

Mefenamic acid passes into breast milk and can affect the baby. You should not breast-feed whilst taking these tablets, unless advised by your doctor.

**Fertility**

If you are trying to become pregnant, do not take these tablets as it may make getting pregnant more difficult. Speak to your doctor if you are trying to become pregnant or are having difficulties getting pregnant.

**Driving and using machines**

Mefenamic Acid Tablets may cause drowsiness, fatigue, dizziness or may affect your vision. If you experience any of these symptoms, you should not drive or operate machinery, or perform any tasks which may require you to be alert.

**Mefenamic Acid Tablets contain lactose and sodium**

- If you have been told by your doctor you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

**3. How to take Mefenamic Acid Tablets**

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

Mefenamic Acid Tablets should preferably be taken with or after food.

**Do not drink alcohol** whilst taking Mefenamic Acid Tablets. Alcohol and smoking may irritate the stomach and make some side effects worse.

**Adults and the elderly**

The usual dose is one tablet, three times a day.

Elderly patients are at a higher risk of side effects and should take the lowest effective dose, for the shortest possible time. Your doctor may perform additional monitoring.

**Use in children**

Mefenamic Acid Tablets are not suitable for children under the age of 12 years.

**If you take more Mefenamic Acid Tablets than you should**

This may harm your stomach and kidneys, and you may suffer from seizures (fits).

If you have taken more tablets than you should, talk to your doctor, pharmacist or nearest hospital emergency department **immediately**. You may require medical attention. This is important even if you feel well.

### **If you forget to take Mefenamic Acid Tablets**

Do not take a double dose to make up for a forgotten tablet. Take the forgotten tablet as soon as you remember, but if it is almost time for your next tablet, skip the missed tablet and continue as usual.

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 Mefenamic Acid Tablets** if you experience any of the following reactions, and **seek medical help immediately**:

#### **Allergic reactions:**

- difficulty in swallowing or breathing, swelling of the face, lips, throat or tongue;
- severe skin itching with a red rash or raised bumps;
- blistering of the eyes, mouth, or genital area, with patch areas of peeling skin or rash;

#### **Other reactions:**

- diarrhoea;
- passing blood in your faeces (stools/motions), or tar-like black faeces;
- vomiting blood or dark particles which look like coffee grounds;

**Seek immediate medical attention** if you have any of the below symptoms:

- indigestion or heartburn, pain in your stomach or abdominal area, feeling sick (nausea), vomiting;
- unusual bleeding or bruising, such as nose bleeds, pinpoint red spots on the skin, purple bruise-like rash in the mouth or on the skin;
- feeling tired, breathless or looking pale, which may be signs of anaemia;
- fever, sore throat, mouth ulcers, repeated or persistent infections, which may be signs of low levels of white blood cells;
- seizures (fits);
- headache, nausea, vomiting, tiredness or muscle cramps which may be signs of low sodium levels;
- sudden headache, stiff neck, fever, sensitivity to bright lights, drowsiness, muscle pain, with or without rash;
- fever, rash, nausea, aches or pains, changes in amount of urine passed, passing red urine, passing urine at night, which may be signs of changes in your kidneys;
- sudden loss of or blurred vision, loss of colour vision, eye pain which worsens on movement of the eye;
- headache, especially on waking in the morning, which may be due to high blood pressure;
- pain behind the ribs which spreads towards the back and worse when lying down, nausea, vomiting, fever, which may be due to inflammation of your pancreas;
- yellowing of the eyes or skin, pale faeces and dark urine, unexplained and persistent nausea, stomach problems, appetite loss, or unusual tiredness, which may be due to changes in your liver.

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

- vertigo (head spinning);
- fatty faeces;
- sweating;
- palpitations (rapid heartbeat);
- mental confusion;
- appetite loss;
- constipation or bloating;
- blurred vision, eye irritation;
- feeling ill (malaise);
- tinnitus (buzzing or ringing in the ears);
- tingling or numbness of the hands or feet;
- if you have diabetes, sudden and poor blood sugar control – your doctor or pharmacist can help measure your blood sugar levels;
- asthma, or asthma which may be worse than usual;
- swelling of your hands or around your ankles/feet;
- mouth pain, which may show as pain or ulcers of the tongue, cheeks, lips, throat or gums;
- dizziness, drowsiness, feeling lethargic and tired;
- symptoms of low blood pressure, e.g. light-headedness;
- reactions to the sun such as red, painful or swollen skin. Whilst taking mefenamic acid, do not use a sun bed, sunbathe or expose your skin to artificial ultraviolet (UV) light;
- depression;
- inability to sleep;
- hallucinations;
- nervousness;
- ear pain.

Medicines such as Mefenamic Acid Tablets may be associated with a small increased risk of stroke or heart attack. (see section 2 “Warnings and Precautions”).

**Urine tests:** Tell the doctor before having a urine test, as this medicine may affect the results.

**Reporting of side effects**

If you get any 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

**5. How to store Mefenamic Acid Tablets**

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

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

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 film-coated Tablets contain:**

- The active substance is mefenamic acid. Each tablet contains 500 mg mefenamic acid.
- The other ingredients are lactose monohydrate, pregelatinised starch, croscarmellose sodium, , povidone, microcrystalline cellulose, colloidal silicone dioxide, magnesium stearate, Opadry II Yellow [hypromellose, lactose monohydrate, titanium dioxide (E 171), macrogol, iron oxide yellow (E 172), talc, iron oxide red (E 172)].
- See section 2 for further information on lactose.

### **What Mefenamic Acid Tablets look like and contents of the pack**

Mefenamic Acid Tablets are yellow coloured, oval shaped, approximately 19.00 mm x 8.90 mm, film-coated tablets, plain on both sides.

The tablets are packed in PVC/PVDC blisters, sealed with aluminium lidding foil. They are available in blister packs of 28, 84 and 100 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

Tillomed Laboratories Limited  
220 Butterfield  
Great Marlings  
Luton  
LU2 8DL  
United Kingdom

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