

## PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

### Mefenamic Acid 500 mg Film-Coated Tablets

**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 inflammation, such as redness and swelling.
- Pain or discomfort associated with arthritis, rheumatoid or muscular disorders.
- Pain after trauma or surgery.
- Muscle or dental pain, headaches.
- Pain after childbirth.
- Painful or heavy periods.

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

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

- if you are allergic to mefenamic acid or any of the other ingredients of this medicine (listed in section 6);
- 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, or have a history of gastrointestinal conditions such as bleeding in the stomach, peptic ulcer, gastritis;
- if you have severe heart, liver or kidney problems;
- if you are more than 6 months pregnant;

- if you have just had heart bypass surgery.

### **Warnings and precautions**

#### **Talk to your doctor 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 aspirin, warfarin or clopidogrel, which thin the blood;
- you are taking antidepressants called Selective Serotonin Re-uptake Inhibitors (SSRIs) such as paroxetine;
- you have liver or kidney problems, as your doctor may monitor their function before and during treatment;
- you are trying to become pregnant (see “Fertility” section);
- you are elderly (see section 3);
- previously taking painkillers such as aspirin have ever given you an upset stomach, or if you have 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 the clotting of your blood (it can make you bleed more and for longer than usual);
- you have or have a history of asthma, as this medicine may cause breathing difficulties;
- you have epilepsy;
- you have a disorder of the connective tissue, such as Systemic Lupus Erythematosus (SLE);
- you are dehydrated (thirsty, dry mouth, dry skin, dark urine, headache);
- you have heart problems, previously had a stroke, or you think that 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 risk is more likely with high doses, and prolonged treatment.

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

#### **Blood tests**

Your doctor may test your blood during treatment.

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

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

Some medicines may be affected by Mefenamic Acid Tablets or they may affect how well Mefenamic Acid Tablets will work.

Tell your doctor or pharmacist if you are taking:

- medicines which can increase the chance of getting ulcers or a bleed in the stomach or gut, such as:
  - medicines used to treat arthritis and inflammation (corticosteroids);
  - medicines used to thin the blood (anti-platelet agents such as warfarin, aspirin, clopidogrel);
  - anti-depressants called Selective Serotonin Re-uptake Inhibitors (SSRIs) such as paroxetine;
  - any other anti-inflammatory medicines, such as diclofenac, celecoxib;
- aspirin (including low doses), used in some heart conditions to prevent 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;
- some medicines used to treat diabetes, such as glibenclamide, glipizide;
- medicines used to suppress the immune system, such as ciclosporin, methotrexate, tacrolimus;
- lithium, a medicine used to treat some types of depression and mood swings;
- a medicine usually prescribed through hospitals, called mifepristone (taken within the last 12 days);
- quinolone or aminoglycoside antibiotics, used to treat infections;
- zidovudine, used for HIV;
- probenecid, used in special cases to protect the kidneys;
- medicines which bind to protein in the blood (check with your pharmacist).

### **Taking Mefenamic Acid Tablets with alcohol**

Avoid drinking alcohol. It may increase your risk of stomach bleeding.

### **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 this medicine.

### **Pregnancy**

Mefenamic acid passes to your unborn baby. You should not take Mefenamic Acid Tablets during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Mefenamic Acid Tablets can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Mefenamic Acid Tablets should **not** be taken in the last three months of pregnancy, as this may harm your unborn child and cause problems at delivery. They can cause kidney and heart

problems in your unborn baby. They may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

### **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 they 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 affect your vision. If you experience any of these symptoms, you should not drive or operate machinery, or perform any tasks that 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 medicine.
- 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 has told you. Check with your doctor or pharmacist if you are not sure.**

Mefenamic Acid Tablets should be taken with or immediately 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, with additional monitoring carried out by their doctor.

### **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**

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

**Symptoms of overdose include:** headache, feeling or being sick (nausea, vomiting), gastrointestinal pain and/or bleeding, diarrhoea, disorientation, feeling excited, coma, drowsiness, ringing in the ears (tinnitus), fainting, fits. In cases of significant overdose, severe kidney failure and liver damage are possible.

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

Take the forgotten tablet as soon as you remember, unless it is time for your next tablet. If you miss a tablet, do not take a double dose to make up for the forgotten tablet.

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 and seek medical advice immediately if you experience any of the following symptoms:**

##### **Allergic reactions:**

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

##### **or any of the following reactions:**

- diarrhoea;
- passing blood in your stools, or passing black tarry stools;
- vomiting blood or dark particles which look like coffee grounds;

**Seek immediate medical advice if you experience any of the following symptoms:**

- indigestion or heartburn, pain in your stomach, feeling or being 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 and 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 with eye movement;
- 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 stools and dark urine, unexplained and persistent nausea, stomach problems, appetite loss, or unusual tiredness, which may be due to changes in your liver;
- worsening of colitis and Crohn's disease;
- elevation of one or more liver function tests;
- failure of various organs at the same time (multi-organ failure);
- heart failure.

### **Other side effects**

#### **Not known (frequency cannot be estimated from the available data):**

- vertigo (head spinning);
- fatty stools;
- sweating;
- palpitations (rapid heartbeat);
- mental confusion;
- appetite loss;
- constipation or bloating;
- blurred vision, eye irritation;
- feeling ill (malaise);
- tinnitus (ringing in the ears);
- tingling or numbness in the hands or feet;
- if you have diabetes, sudden and poor blood sugar control – your doctor or pharmacist can measure your blood sugar levels;
- asthma, or asthma that is worse than usual;
- swelling of your hands or around your ankles/feet;
- sore mouth (pain or ulcers of the tongue, cheeks, lips, throat or gums);
- dizziness, drowsiness, feeling lethargic and tired;
- signs of low blood pressure, such as light-headedness;
- reactions to the sun such as red, painful or swollen skin. 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 after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Mefenamic Acid 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)].

### **What Mefenamic Acid Tablets looks 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

**This leaflet was last revised in 10/2023.**