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**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 any of the 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 is and what it is 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 is and what it is used for

Mefenamic acid tablets contain mefenamic acid which is a non-steroidal anti-inflammatory drug (NSAID).

They can help to relieve:
- symptoms of inflammation, such as redness and swelling
- pain and discomfort caused by arthritis, muscular or rheumatic disorders
- headache, muscle ache or toothache
- pain after operations, trauma
- childbirth pain
- 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) or any other NSAIDs e.g. ibuprofen, aspirin
- have, or have ever had, stomach or intestinal conditions such as peptic ulcer, bleeding in the stomach or severe gastritis
- have an inflammatory bowel disease (e.g. ulcerative colitis, Crohn's disease)
- have severe heart, liver or kidney problems
- have just had heart bypass surgery
- are more than 6 months pregnant.

If any of the above apply to you, speak to your doctor or pharmacist.

Take special care with Mefenamic acid

**Warnings and precautions**

Talk to your doctor before taking this medicine, if you:
- are taking any other NSAIDs (e.g. ibuprofen, diclofenac)
- are taking any other anti-inflammatory medicines including steroids (e.g. prednisolone)
- are taking aspirin or medicines that thin the blood (e.g. warfarin, clopidogrel)
- are taking antidepressants called selective serotonin re-uptake inhibitors (SSRIs) (e.g. paroxetine)
- have kidney or liver problems. Your doctor may check your kidney or liver function before and during treatment
- are elderly (see Section 3)
- are trying to become pregnant (see Section on Fertility)
- have stomach or digestive tract problems or if you have ever had an upset stomach after taking pain killers such as aspirin. Bleeding in the stomach or gut can occur in patients taking Mefenamic acid
- have a bleeding disorder or if you are going to have a major operation Mefenamic acid can affect the clotting of your blood. It can make you bleed more and for longer than usual
- have asthma, or a history of asthma, as this medicine may cause breathing difficulties
- have a connective tissue disorder, e.g. Systemic Lupus Erythematosus (SLE)
- have epilepsy
- are dehydrated (thirsty with dry skin, dark urine, dry mouth, headache)
- 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). Additional monitoring may be carried out by your doctor.

Medicines such as Mefenamic acid may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses and prolonged treatment. **Do not exceed** the recommended dose or duration of treatment.

**Other medicines and Mefenamic acid tablets**

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

Some medicines may be affected by Mefenamic acid or they may affect how well Mefenamic acid will work. Tell your doctor or pharmacist if you are taking:
- medicines that can increase the chance of getting ulcers or a bleed in the stomach or gut, such as:
  - corticosteroids used to treat arthritis and inflammation
  - medicines such as anti-platelet agents, used to thin the blood (e.g. warfarin, aspirin, clopidogrel)
  - antidepressants called selective serotonin reuptake inhibitors (SSRIs) (e.g. paroxetine)
  - any other anti-inflammatory medicines (e.g. diclofenac, celecoxib)
- aspirin including low doses of aspirin used to prevent your blood from clotting in certain heart conditions.
- medicines used for high blood pressure (e.g. atenolol, ramipril, valsartan)
- diuretics (water tablets) or heart medicines (e.g. digoxin, sotalol, diltiazem)
- some diabetic medicines such as (e.g. glipizide, glibenclamide)
- medicines which suppress the immune system (e.g. ciclosporin, tacrolimus, methotrexate)
- lithium, a medicine used to treat mood swings and some types of depression
- a medicine usually prescribed through hospitals, called mifepristone (taken within the last 12 days)
- quinolone antibiotics (antibiotics used to treat infections)
- aminoglycoside antibiotics, used under medical supervision in hospitals
- zidovudine, a medicine used for HIV
- probenecid, a medicine used in special cases, to protect the kidneys
- medicines which bind to protein in the blood (check with your pharmacist).

**Blood tests**

Your doctor may test your blood during treatment.

**Pregnancy, breast-feeding and fertility**

Pregnancy

Mefenamic acid will be passed to your unborn baby. It is not known how much it will affect your unborn baby in the first 6 months of pregnancy.

DO NOT take the mefenamic acid tablets if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take mefenamic acid 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 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.

They may also increase the likelihood of bleeding in the mother and in the baby.

If you need to take these tablets, your doctor can help you decide whether or not to take them during the first 6 months of pregnancy.

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.

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

**Driving and using machines**

Mefenamic acid may cause drowsiness, dizziness, fatigue or affect your vision. If any of these occur do not drive, use machinery, or perform any tasks that may require you to be alert.

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Size : Min. 9pt., Max. 14pt.

Front Page

NON PRINTING COLOUR

**MFG. LOCATION: PONDY**

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|---|---|---|---|---|---|
| **Product** | **Mefenamic acid 500 mg film-coated tablets** | | | | |
| Buyer/Country | SPUK | Component | Pack Insert | | |
| **Dimension** | **150 x 420 mm** | | | Pack | NA |
| **New Item Code** | **1050658** | Old Item Code | 1048890 | | |
| Colour Shades | BLACK | | | No. of Colours | 1 |

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| Change Control No. | PC-PYF/2024/132 - Record Number: 422551 | Artwork Version | 3.0 |
| Design/Style | Front & Back Printing, to be supplied in folded size of 150 x 35 mm. Product name appearing front side after final folding. | | |
| Substrate | 40 GSM Bible Paper. | | |
| Special Instructions | PRINTING CLARITY TO BE CLEAR AND SHARP. | | |
| Autocartonator Requirements | NA | | |

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**Mefenamic acid tablets** contain lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### 3. How to take Mefenamic acid tablets

Always take Mefenamic Acid tablets exactly as your doctor or pharmacist has told you. Your doctor will decide on the appropriate dose to suit your condition. Check with your doctor or pharmacist if you are not sure.

- Take the tablets with or immediately after a **meal**.
- Do not drink **alcohol** while taking Mefenamic acid tablets. Alcohol and smoking can irritate the stomach and make some of the side effects worse.

**Dosage:**

**Adults and the elderly:** The usual dose is 1 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.

**Children:** This medicine is NOT suitable for children under 12 years.

**If you take more than you should**

If you take more tablets than you should, you may harm your stomach, kidneys and you may get seizures (fits).

1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the container and any remaining tablets with you so that people can see what you have taken.
3. Do this even if you feel well.

**If you forget to take**

If you forget to take a dose take it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual.

Do not take a double dose to make up for a missed dose.

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

### 4. Possible side effects

Like all medicines, Mefenamic Acid tablets can cause side effects, although not everybody gets them. Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised lumps
- blistering of the mouth, eyes, and genital region, and patchy areas of rash, peeling skin **or** any of the following reactions
- diarrhoea
- passing blood in your stools (faeces/motions)
- passing black tarry stools
- vomiting any blood or dark particles that look like coffee grounds.

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

- indigestion or heartburn, abdominal pain (pain in your stomach) or other abnormal stomach symptoms, nausea (feeling sick), vomiting
- any unusual bruising or bleeding, for example nose-bleeds, pinpoint red spots on the skin, unusual purple bruise-like rash on the skin or in the mouth
- signs of anaemia such as feeling tired, breathless, and looking pale
- fever, sore throat, mouth ulcers, repeated infections or infections that will not go away. This may be due to a low level of white blood cells
- seizures (fits)
- signs of low sodium levels such as headache, nausea, vomiting, tiredness, muscle cramps
- sudden headache, stiff neck, fever, sensitivity to bright light, drowsiness and muscle pain, with or without a rash
- fever, rash, nausea, aches and pains, passing more or less urine than usual, passing red urine or passing urine at night. This may be due to changes in your kidneys
- sudden loss or blurring of vision, loss of colour vision, eye pain which worsens with eye movement
- headache, in particular on waking in the morning. This may be due to high blood pressure
- pain behind the ribs radiating towards the back, often worse when lying down, nausea, vomiting, fever. This may be due to inflammation of your pancreas
- yellowing of your skin or eyes, pale faeces and dark urine, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness. This may be due to changes in your liver.

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

- head-spins (vertigo)
- fatty stools
- sweating
- rapid heartbeat (palpitations)
- mental confusion
- loss of appetite
- constipation or bloating
- blurred vision, eye irritation
- feeling ill (malaise)
- ringing or buzzing in the ears (tinnitus)
- numbness or tingling in hands or feet
- sudden poor blood sugar control if you have diabetes. Your doctor or pharmacist can measure your sugar levels
- asthma or asthma that is worse than usual
- swelling of your hands and feet (around the ankles)
- sore mouth (pain or ulcers on 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. Your skin may become red, painful and swollen
- do not sunbathe, use a sun bed, or expose your skin to artificial UV light.
- depression
- inability to sleep
- hallucinations
- nervousness
- ear pain

Medicines such as Mefenamic acid may be associated with a small increased risk of heart attack or stroke. (See Section 2 - end of 'Take special care').

**Urine tests**: Tell the doctor if you are having urine tests, as your 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

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side affects 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.

Store below 25°C.

Do not use this medicine if you notice your tablets become discoloured or show any sign of deterioration, return them to your pharmacist.

Medicines should not be disposed 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 Tablets contain**

Each tablet contains 500 mg of mefenamic acid.

The other ingredients are lactose monohydrate, pregelatinized starch, croscarmellose sodium, povidone, purified water, microcrystalline cellulose, colloidal silicon dioxide and magnesium stearate.

The film-coating material (Opadry Yellow) contains: hypromellose, lactose monohydrate, titanium dioxide (E171), macrogol, iron oxide yellow (E172), talc and iron oxide red (E172).

**What Mefenamic Acid Tablets looks like and contents of the pack**

Mefenamic acid 500 mg film-coated tablets are yellow coloured, oval shaped film coated tablets plain on both the sides.

Mefenamic acid come in blister packs of 10, 28, 56, 84 and 100 tablets.
Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer:**

Strides Pharma UK Ltd
Unit 4, The Metro Centre, Dwight Road,
Watford, WD18 9SS
United Kingdom

**This leaflet was last revised in 11/2022.**

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Back Page

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