Package leaflet: Information for the user

Mefenamic Acid 50 mg/5 ml Suspension

ESSENT!AL GENERICS

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Read all of this leaflet carefully before you start using 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. Do not pass it on to others. It may harm them, even if their symptoms 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 Suspension is and what it is used for**
2. **What you need to know before you take Mefenamic Acid Suspension**
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1. What Mefenamic Acid Suspension is and what it is used for

Mefenamic Acid Suspension contains mefenamic acid which is a non-steroidal anti-inflammatory drug (NSAID). This product is intended for children but may be given to adults.
It can help to relieve:
- symptoms of inflammation, such as redness and swelling
- pain and discomfort caused by arthritis, muscular or rheumatic disorders
- headache or toothache
- pain after operations, trauma
- fever in children
- painful or heavy periods in girls.

2. What you need to know before you take Mefenamic Acid Suspension

Do not take Mefenamic Acid Suspension
- if you are allergic to mefenamic acid, to any other anti-inflammatory medicines (such as aspirin, ibuprofen, celecoxib), or to any of the other ingredients (listed in section 6)
- if you have, or have ever had, stomach or intestinal conditions such as peptic ulcer, bleeding in the stomach or severe gastritis
- if you have an inflammatory bowel disease (e.g. ulcerative colitis, Crohn's disease)
- if you have severe heart, liver or kidney problems
- if you have just had heart bypass surgery
- if you are more than 6 months pregnant.

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Mefenamic Acid Suspension:
- if you are taking any other NSAIDs (e.g. ibuprofen, diclofenac)
- if you are taking any other anti-inflammatory medicines including steroids (e.g. prednisolone)
- if you are taking aspirin or medicines that thin the blood (e.g. warfarin, clopidogrel)
- if you are taking antidepressants called selective serotonin re-uptake inhibitors (SSRIs) (e.g. paroxetine)
- if you have kidney or liver problems. Your doctor may check your kidney or liver function before and during treatment
- if you are elderly (see section 3)
- if you are trying to become pregnant (see section on Fertility)
- if you have stomach or digestive tract problems or if you 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
- if you 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
- if you have asthma, or a history of asthma, as this medicine may cause breathing difficulties
- if you have a connective tissue disorder, e.g. Systemic Lupus Erythematosus (SLE)
- if you have epilepsy
- if you are dehydrated (thirsty with dry skin, dark urine, dry mouth, headache)
- if you 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
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
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 re-uptake 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 (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
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.

Pregnancy
Mefenamic acid will be passed to your unborn baby. 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.
DO NOT take the suspension in the last 3 months of pregnancy as it may harm your unborn child and 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.

Breast-feeding
Mefenamic acid passes into breast milk and can affect the baby. You should not take the suspension while breast-feeding unless advised by your doctor.

Fertility
DO NOT take the suspension if you are trying to become pregnant, as it may make it more difficult to get pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

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.

Mefenamic Acid Suspension contains:
- **Ethanol (alcohol)**
  This medicine contains 26 mg of alcohol (ethanol) in each 5 ml suspension which is equivalent to 5.2 mg/ml. The amount in 5 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- **Propylene glycol (E 1520)**
  This medicine contains 11 mg propylene glycol (E 1520) in each 5 ml suspension which is equivalent to 2.15 mg/ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.
- **Sodium**
  This medicine contains 14 mg sodium (main component of cooking/table salt) in each 5 ml suspension. This is equivalent to 0.68% of the recommended maximum daily dietary intake of sodium for an adult.
- **Sodium Benzoate (E 211)**
  This medicine contains 25 mg sodium benzoate (E 211) in each 5 ml suspension which is equivalent to 5 mg/ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- **Sorbitol (E 420)**
  This medicine contains 530 mg sorbitol (E 420) in each 5 ml suspension which is equivalent to 106 mg/ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a

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rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- **Sucrose**
  Contains 1 g of sucrose per 5 ml suspension. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to your teeth.

3. How to take Mefenamic Acid Suspension

Always take this medicine exactly as your doctor 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.
- Shake the bottle before taking the medicine.
- Take the suspension with or immediately after a **meal.**
- After taking the suspension, rinse the mouth - this medicine contains sucrose which may be harmful to the teeth if taken for more than 2 weeks.
- Do not drink **alcohol** while taking Mefenamic Acid. Alcohol and smoking can irritate the stomach and make some of the side effects worse.

Dosages

Adults and the elderly
This medicine is intended for children. Contact your doctor for dosage advice if you are an adult taking this suspension.
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
The recommended dose may be given up to 3 times per day.

Age	Usual Dose
6 months to 2 years	5 ml
2 years to 5 years	10 ml
5 years to 9 years	15 ml
9 years to 12 years	20 ml

Do not take Mefenamic Acid for more than 7 days unless advised to do so by your doctor.

If you take more Mefenamic Acid than you should
If you take more of the suspension than you should, you may harm your stomach, kidneys and you may get seizures (fits). Symptoms of overdose may also include headache, nausea, stomach pain, vomiting, rarely diarrhoea, disorientation, excitation, coma (loss of consciousness for a period of time), tiredness, ringing in the ears, fainting and occasionally convulsions.
1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the bottle and any remaining suspension with you so that people can see what you have taken.
3. Do this even if you feel well.

If you forget to take Mefenamic Acid Suspension
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 forgotten dose.
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. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Stop taking the suspension 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, 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
- low body temperature (below 35°C), feeling cold with pale-looking skin, especially in children.

The side effects listed below have been reported:
Not known: frequency cannot be estimated from the available data.
- head-spins (vertigo)
- hallucinations
- rapid heartbeat (palpitations)
- mental confusion
- 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
- nervousness
- sweating
- fatty stools
- loss of appetite
- 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 'Warnings and precautions').

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 at: 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 Suspension

- Keep this medicine out of the sight and reach of children.
- Do not take after the expiry date which is stated on the bottle label and on the carton after EXP. The expiry date refers to the last day of that month.
- Store below 30°C.
- Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicine you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Mefenamic Acid Suspension contains
- The active substance is mefenamic acid (50 mg per 5 ml).
- The other ingredients are
  aluminium magnesium silicate, povidone, sodium hydroxide, glucono delta lactone, hydrochloric acid, sorbitol (E 420), sodium benzoate (E 211), saccharin sodium, sucrose, caramellose sodium, ethanol (alcohol), banana flavour (contains propylene glycol (E 1520)), anise mint, chocolate flavour (contains propylene glycol (E 1520)) and purified water.
  (see end of section 2 for further information on ethanol, propylene glycol, sodium, sodium benzoate, sorbitol, and sucrose).

What Mefenamic Acid Suspension looks like and contents of the pack
Mefenamic Acid Suspension is an off-white suspension with typical aroma and taste. It is available in an amber glass bottle of 30 and 125 ml.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Chemidex Pharma Ltd, trading as Essential Generics,
8a Crabtree Road, Egham, Surrey, TW20 8RN,
United Kingdom.

Manufacturer
Delpharm Bladel BV, Industrieweg 1, 5531 AD Bladel, the Netherlands.

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