

## **Meflam 250**

### **PATIENT INFORMATION LEAFLET**

**Read all of this leaflet carefully before you start taking this medicine.**

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What are Meflam 250 Capsules and what they are used for
2. Before you take Meflam 250 Capsules
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#### **1. WHAT ARE Meflam 250 CAPSULES AND WHAT ARE THEY USED FOR**

Meflam 250 Capsules belongs to a group of medicines called non-steroid anti-inflammatory drugs (NSAIDs). These medicines reduce pain and inflammation, and bring down a high temperature. Meflam 250 Capsules are most commonly used for relief of mild to moderate pain including muscle pains and pain after injury, headaches and toothaches, period pains and pain following an operation or

after 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. BEFORE YOU TAKE MEFLAM 250 CAPSULES**

### **DO NOT take Meflam 250 Capsules if:**

- You know that you are allergic to Meflam 250 or any of the other ingredients in these Capsules (listed at the end of this leaflet)
- You currently have a stomach ulcer or bleeding
- You have suffered from stomach ulcers or bleeding two or more times in the past
- You suffer from inflammatory bowel disease
- You show any signs of allergy (such as asthma, hay fever or skin rash) to aspirin, ibuprofen or other NSAIDs. An allergic reaction may include swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- You have severe problems with your kidneys or liver
- You suffer from severe heart failure
- You had a major heart surgery
- You are in the last three months of pregnancy.

**Take special care with Meflam 250 Capsules and check with your doctor or pharmacist before taking your medicine if:**

- You have had an ulcer or some other problem affecting your stomach, or intestines
- You have asthma or wheezing attacks (or if you have had asthma in the past)
- You have any heart, liver or kidney problems
- You are elderly
- You suffer from epilepsy (fits)
- You suffer from any abnormality of the blood
- You are dehydrated (for example you have been losing fluid through vomiting, diarrhoea or passing too much or too little, urine (fluids))
- You have frequent headaches
- You drink alcohol

You have a connective tissue disorder e.g. Systemic Lupus Erythematosus (SLE) resulting in joint pain, skin change and disorders of other organs

- You have a problem with the metabolism of sugar in your body
- You are trying to get pregnant (see section on pregnancy).

If you are having a medical examination, tell the doctor that you are taking Meflam 250 Capsules as they reduce the signs of fever and inflammation which would otherwise be noticed.

Medicines such as Meflam 250 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**

Please tell your doctor or pharmacist if you are taking or recently have taken any other medicines, including medicines obtained without a prescription.

### **Meflam 250 Capsules may affect or be affected by the following medicines**

- Anticoagulants (drugs used to thin the blood to prevent blood clots, e.g. warfarin, heparin)
- Antiplatelet tablets (to prevent blood clots, e.g. clopidogel)
- Antihypertensives (for the treatment of high blood pressure)
- Diuretics (to make you pass more water)
- Lithium (for depression)
- Medicines for the treatment of heart conditions (e.g. digoxin)
- Quinolone antibiotics (for an infection e.g. ciprofloxacin, norfloxacin and nalidixic acid)
- Any other NSAID (for painful or inflammatory conditions e.g. aspirin, COX-2 selective inhibitors like valdecoxib, paracoxib and refocoxib, ibuprofen)

- Mifepristone (used to terminate pregnancies)
- Methotrexate (which can be used to treat certain tumours and other diseases including psoriasis and rheumatoid arthritis)
- Ciclosporin or tacrolimus (used to suppress the body's immune system, e.g. following transplants or in diseases such as psoriasis and rheumatoid arthritis)
- Corticosteroids (used for the treatment of asthma and various inflammatory conditions e.g. beclomethasone)
- Probenecid used in treatment of swollen joints
- Drugs used in diabetes (e.g. glibenclamide)
- Drug used as antibiotics ( e.g. Gentamycin, Neomycin, Kanamycin)
- Zidovudine (an anti-viral drug)
- SSRIs such as fluoxetine or sertraline (for depression).

### **Pregnancy and breast feeding**

Ask your doctor or pharmacist for advice before taking any medicine. Meflam 250 Capsules may make it difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant. Meflam 250 Capsules should, if possible not be taken during pregnancy. It is possible that you may be able to take Meflam 250 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 drowsiness dizziness, weakness and visual disturbances. If you notice any such symptoms, do not drive or operate machinery and ask your doctor or pharmacist for advice.

### **Important information about some of the ingredients of Meclam 250 Capsules**

This medicine also contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

### **3. HOW TO TAKE MEFLAM 250 CAPSULES**

Make sure you take your Capsules exactly as directed by your doctor. The instructions will be written on the label. You should check with your doctor or pharmacist if you are not sure. Meclam 250 Capsules should be taken with or after food. The capsules should be swallowed whole with water. Do not chew them or break them.

**Adults:** The usual dose is two Capsules three times each day. For excessively heavy periods, start taking your medicine on the first day of excessive bleeding and continue as directed by your doctor. For period pains, start taking your medicine when you first notice the pain and continue as directed by your doctor. As a general principle, the smallest effective dose should be used.

**Elderly:** The adult dose can be used, although these Capsules should be used with caution in patients suffering from dehydration or kidney failure.

**Children:** Meclam 250 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 Meclam 250 Capsules than you should:**

If you (or someone else) take too many of these capsules, you may experience headache, nausea, vomiting, pain in abdomen, blood in stool or vomiting, diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing in ear, fainting, occasionally convulsions. In cases of significant poisoning acute kidney failure and liver damage are possible. Contact your doctor, or hospital immediately for advice. Bring the container with any remaining Capsules with you.

**If you forget to take your Meclam 250 Capsules:**

If you miss a dose, leave it out and take the next dose whenever it is due. After that, just carry on as before. Do not take double the dose. If you have any further questions about these Capsules, ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines Meclam 250 can cause side effects, although not everybody gets them.

**All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately. Do not take if you have a peptic ulcer (ulcer in your stomach, or intestines) or bleeding in your stomach, or have had two or more episodes of peptic ulcer, stomach bleeding or perforation.**

**STOP TAKING** the medicine and tell your doctor if you experience:

- Indigestion or heart burn
- Abdominal Pain (pains in your stomach) or other abdominal (stomach) symptoms.

If you suffer from any of the following at anytime during your treatment

**STOP TAKING** the medicine and see a doctor immediately.

- Pass blood in your stools/motions
- Pass loose stool (Diarrhoea)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds.

**Other Side Effects:**

- Mouth ulcers, malaise, fatigue, unexplained bruising, fever or sore throat may occasionally occur, if you notice any of these symptoms speak to your doctor as they may be signs of a blood disorder
- If a skin rash or jaundice (yellowing of the skin or whites of eyes) occurs, tell your doctor
- Nausea (feeling sick), vomiting (being sick), loss of appetite
- Fits
- Rapid heart beats
- Reactions to the sun



- You may notice urinary symptoms such as blood in the urine or an increase or decrease in the amount of urine, ankle swelling, reduced salt levels in the body
- Symptoms such as sleep disturbance, depression, confusion, nervousness, hallucinations (imagining sensations), noise in the ears or impaired hearing, vertigo, dizziness, tingling or other odd sensations, problems with your eyesight or drowsiness have occasionally been reported
- Symptoms of aseptic meningitis such as, over-reaction of the skin to sunlight, persistent headache, a stiff neck, fever, drowsiness or muscle pain may occur in some patients (especially in patients with existing auto immune disorders, such as systemic lupus erythematosus, mixed connective tissue disease)
- Medicines such as Meflam 250 may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. If you have heart problems, previous stroke or think that you might 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.

Your doctor may try to minimise any undesirable effect by giving you the lowest effective dose of Meflam 250 Capsules for the shortest amount of time necessary to control your symptoms.

**If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

## **5. HOW TO STORE MEFLAM 250 CAPSULES**

Keep out of the reach and sight of children

Do not use Meflam 250 Capsules after the expiry date which is stated on the label. The expiry date refers to the last day of that month. They should be stored in a cool, dry place, below 25°C. Keep in original container to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Remember:**

This medicine is for you. Only a doctor can prescribe it for you. Never give this medicine to someone else, it could harm them, even if their symptoms seem the same as yours.

**6. FURTHER INFORMATION**

**What Meflam 250 Capsules contain:**

Each Meflam 250 Capsule contains 250mg of the active substance, Mefenamic Acid.

The other ingredients are maize starch, lactose, purified water, magnesium stearate, sodium starch glycollate, sodium lauryl sulphate.

**What Meflam 250 Capsules look like and contents of the pack:**

Meflam 250 Capsules are hard gelatin capsules with a blue cap and yellow body. They are packed in polypropylene securitainers with child proof lids (50, 84, 100, 168 and 500 capsules). Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer:**

Mercury Pharmaceuticals Ltd,

No. 1 Croydon, 12-16 Addiscombe Road, Croydon CR0 0XT, UK.

This leaflet was last revised in September 2012.