

**MEFENAMIC ACID 250MG CAPSULES  
PL 04556/0045**

**UKPAR**

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**MEFENAMIC ACID 250MG CAPSULES**  
**PL 04556/0045**

**LAY SUMMARY**

The MHRA granted Pharmvit Limited a Marketing Authorisation (licence) for the medicinal product Mefenamic Acid 250mg Capsules on 10<sup>th</sup> August 2006. This product, to be available by prescription only (POM), contains mefenamic acid and is used for the relief of pain and discomfort caused by arthritis, muscular pain, headache, periods, toothache and fever in children.

The active ingredient mefenamic acid is part of a group of medicines called non-steroidal anti-inflammatory drugs, which cause a reduction in the levels of prostaglandins, substances believed to be responsible for causing pain and inflammation.

This application is a duplicate of a previously granted application for Mefenamic Acid BP Capsules 250mg/Mendys Capsules BP 250mg (PL 00790/0100), for which the marketing authorisation holder is Clonmel Healthcare Limited and which was granted on 27<sup>th</sup> May 1992.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Mefenamic Acid 250mg Capsules outweigh the risks, hence a Marketing Authorisation has been granted.

**MEFENAMIC ACID 250MG CAPSULES  
PL 04556/0045**

**SCIENTIFIC DISCUSSION**

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## **INTRODUCTION**

The UK granted a marketing authorisation for the medicinal product Mefenamic Acid 250mg Capsules (PL 04556/0045) to Pharmvit Limited on 10<sup>th</sup> August 2006. The product is available as a prescription only medicine (POM).

The application was submitted as a simple abridged application according to Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC, cross-referring to Mefenamic Acid BP Capsules 250mg/Mendys Capsules BP 250mg (PL 00790/0100), approved on 27<sup>th</sup> May 1992 to the marketing authorisation holder Clonmel Healthcare Limited.

No new data was submitted nor was it necessary for this simple application, as the data are identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no PAR was generated for it.

The active ingredient mefenamic acid acts as an anti-inflammatory analgesic reducing the levels of prostaglandins. Mefenamic Acid 250mg Capsules is indicated for the following:

1. As an anti-inflammatory analgesic for the symptomatic relief of rheumatoid arthritis (including Still's disease), osteoarthritis, and pain including muscular, traumatic and dental pain, headaches of most aetiology, post-operative and post-partum pain; pyrexia in children.
2. Primary dysmenorrhoea.
3. Menorrhagia due to dysfunctional causes and presence of an IUD when other pelvic pathology has been ruled out.

## **PHARMACEUTICAL ASSESSMENT**

**LICENCE NO:** PL 04556/0045

**PROPRIETARY NAME:** Mefenamic Acid 250mg Capsules

**ACTIVE(S):** Mefenamic acid

**COMPANY NAME:** Pharmvit Limited

**E.C. ARTICLE:** Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC

**LEGAL STATUS:** POM

### **1. INTRODUCTION**

This is a simple, piggy back application for Mefenamic Acid 250mg Capsules submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is Pharmvit Limited, Unit 13, Metropolitan Centre, Derby Road, Greenford, Middlesex, UB6 8UJ.

The application cross-refers to Mefenamic Acid BP Capsules 250mg/Mendys Capsules BP 250mg (PL 00790/0100), approved on 27<sup>th</sup> May 1992 to the marketing authorisation holder Clonmel Healthcare Limited. The current application is considered valid.

### **2. MARKETING AUTHORISATION APPLICATION FORM**

#### **2.1 Name(s)**

The proposed name of the product is Mefenamic Acid 250mg Capsules. The product has been named in line with current requirements.

#### **2.2 Strength, pharmaceutical form, route of administration, container and pack sizes**

The product contains mefenamic acid, equivalent to 250mg. It is to be stored in a polypropylene tube with a low density polyethylene cap or a polypropylene tube with a child-resistant high density polyethylene cap. The proposed shelf-life (3 years) and storage conditions (store below 30 degrees) are consistent with the details registered for the cross-reference product.

#### **2.3 Legal status**

On approval, the products will be available as prescription-only medicines (POM).

#### **2.4 Marketing authorisation holder/Contact Persons/Company**

Pharmvit Limited, Unit 13, Metropolitan Centre, Derby Road, Greenford, Middlesex, UB6 8UJ.

The QP responsible for pharmacovigilance is stated and his CV is included.

#### **2.5 Manufacturers**

The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

#### **2.6 Qualitative and quantitative composition**

The proposed composition is consistent with the details registered for the cross-reference product.

## **2.7 Manufacturing process**

The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

## **2.8 Finished product/shelf-life specification**

The proposed finished product specification is in line with the details registered for the cross-reference product.

## **2.9 Drug substance specification**

The proposed drug substance specification is consistent with the details registered for the cross-reference product.

## **2.10 TSE Compliance**

With the exception of lactose monohydrate and gelatin, no materials of animal or human origin are included in the product. This is consistent with the cross reference product.

Lactose monohydrate is sourced from milk that is fit for human consumption and no animal materials, with the exception of bovine rennet, have been used in its manufacture. The applicant has provided TSE certificates of suitability to show that gelatin is sourced from appropriate sources.

## **3. EXPERT REPORTS**

The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

## **4. PRODUCT NAME & APPEARANCE**

See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

## **5. SUMMARY OF PRODUCT CHARACTERISTICS**

The proposed summary is consistent with the details registered for the cross-reference product.

## **6. PATIENT INFORMATION LEAFLET/CARTON**

### PIL

The patient information leaflet has been prepared in-line with the details registered for the cross-reference product.

### Carton and blister

The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

## **7. CONCLUSIONS**

The data submitted with the application are acceptable. A Marketing Authorisation should be granted.

## **PRECLINICAL ASSESSMENT**

No new preclinical data have been supplied with this application and none are required for an application of this type.



## **CLINICAL ASSESSMENT**

As this is a duplicate application, no new clinical data have been supplied and none are required.

## **OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT**

### **QUALITY**

The data for this application are consistent with that previously assessed for the cross-reference product and as such have been judged to be satisfactory.

### **PRECLINICAL**

No new preclinical data were submitted and none are required for an application of this type.

### **EFFICACY**

This application is identical to a previously granted application for Mefenamic Acid BP Capsules 250mg/Mendys Capsules BP 250mg (PL 00790/0100).

No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

### **RISK BENEFIT ASSESSMENT**

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. Extensive clinical experience with mefenamic acid is considered to have demonstrated the therapeutic value of the compound. The risk:benefit is, therefore, considered to be positive.

**MEFENAMIC ACID 250MG CAPSULES**  
**PL 04556/0045**

**STEPS TAKEN FOR ASSESMENT**

1	The MHRA received the marketing authorisation application on 11/06/2002.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 21/06/2002.
3	Following assessment of the application the MHRA requested further information on 26/09/2002 and 29/07/2005.
4	The applicant responded to the MHRA's requests, providing further information on 11/11/2002 and 29/06/2006
5	The application was determined on 10/08/2006

**MEFENAMIC ACID 250MG CAPSULES  
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**STEPS TAKEN AFTER ASSESSMENT**

<b>Date submitted</b>	<b>Application type</b>	<b>Scope</b>	<b>Outcome</b>

# MEFENAMIC ACID 250MG CAPSULES

## PL 04556/0045

### SUMMARY OF PRODUCT CHARACTERISTICS

#### 1 NAME OF THE MEDICINAL PRODUCT

Mefenamic Acid 250 mg Capsules

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 250 mg Mefenamic Acid PhEur.

For full list of excipients see section 6.1

#### 3 PHARMACEUTICAL FORM

Capsules for oral use.

Appearance: Hard gelatin capsule with a blue cap and a brown body, printed with PV and the code “M250.”

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

1. As an anti-inflammatory analgesic for the symptomatic relief of rheumatoid arthritis (including Still’s disease), osteoarthritis, and pain including muscular, traumatic and dental pain, headaches of most aetiology, post-operative and post-partum pain; pyrexia in children.
2. Primary dysmenorrhoea.
3. Menorrhagia due to dysfunctional causes and presence of an IUD when other pelvic pathology has been ruled out.

##### 4.2 Posology and method of administration

The capsules should be swallowed with a drink of water. To be taken preferably with or after food.

*Adults:* 2 capsules (500 mg) three times daily, *to be taken with or after food*

In menorrhagia to be administered on the first day of excessive bleeding and continued according to the judgement of the physician.

In dysmenorrhoea to be administered at the onset of menstrual pain and continued according to the judgement of the physician.

*Elderly (over 65 years):* The elderly are at increased risk of the serious consequences of adverse reactions. If an NSAID is considered necessary, the lowest dose should be used and for the shortest possible duration. The patient should be monitored regularly for gastro-intestinal bleeding during NSAID therapy.

*Children (under 12 years):* Not recommended.

*Administration:* Oral, the capsules should be swallowed with a drink of water.

##### 4.3 Contraindications

Hypersensitivity to any of the constituents. Mefenamic acid should not be administered to patients with renal or hepatic impairment, inflammatory bowel disease or patients with a history of, or active, peptic ulceration.

NSAIDs are contraindicated in patients who have previously shown hypersensitivity reactions (asthma, rhinitis, or urticaria) in response to ibuprofen, aspirin, or other non-steroidal anti-inflammatory drugs.

Because the potential exists for cross-sensitivity to aspirin or other non-steroidal anti-inflammatory drugs, mefenamic acid should not be given to patients in whom these drugs induce symptoms of bronchospasm, allergic rhinitis, or urticaria.

History of upper gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.

Use with concomitant NSAIDs including cyclo oxygenase 2 specific inhibitors (See section 4.5 Interactions).

#### **4.4 Special warnings and precautions for use**

*In all patients:*

Undesirable effects may be minimised by using the minimum effective dose for the shortest possible duration

*Elderly:*

The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation, which may be fatal (See section 4.2-Posology and administration).

*Respiratory disorders:*

Caution is required if administered to patients suffering from, or with a previous history, bronchial asthma since NSAIDs have been reported to precipitate bronchospasm in such patients.

*Cardiovascular, Renal and Hepatic Impairment:*

The administration of NSAIDs may cause a dose dependent reduction in prostaglandin formation and precipitate renal failure. Patients at great risk of this reaction is those with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics and elderly. Renal function should be monitored in these patients (See also section 4.3-Contraindication)

Caution in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with NSAID therapy.

*Gastrointestinal bleeding, ulceration and perforation:*

GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious GI events.

Patients with a history of GI toxicity, particular when elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment.

Caution should be advised in patients receiving concomitant medications, which could increase the risk of gastrotoxicity or bleeding, such as Corticosteroids, or anticoagulant such as warfarin or anti-platelet agents such as aspirin (See section 4.5 Interactions).

When GI bleeding or ulceration occurs in patients receiving mefenamic acid, the treatment should be withdrawn.

NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated (See section 4.8 –Undesirable effects.).

*SLE and mixed connective tissue disease:*

In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis (See section 4.8 – Undesirable effects).

*Female fertility:*

The use of mefenamic acid may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of mefenamic acid should be considered.

Precaution should be taken in patients suffering from dehydration.

In dysmenorrhoea and menorrhagia lack of response should alert the physician to investigate other causes.

Caution should be exercised when treating patients suffering from epilepsy.

Patient with rare hereditary problems of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Each capsule contains 450 micrograms of sodium.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Care should be taken in patients treated with any of the following drugs as interactions have been reported in some patients.

*Anti-hypertensives:* Reduced anti-hypertensive effect.

*Diuretics:* Reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

*Cardiac glycosides:* Mefenamic acid may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycoside levels.

*Lithium:* Decreased elimination of lithium.

*Methotrexate:* Decreased elimination of methotrexate.

*Ciclosporin:* Increased risk of nephrotoxicity with NSAIDs.

*Mifepristone:* NSAIDs should not be used for 8 - 12 days after mifepristone administration as NSAIDs can reduce the effects of mifepristone.

*Other analgesics:* Avoid concomitant use of two or more NSAIDs (including aspirin) as this may increase the risk adverse effects (see section 4.3-Contraindication).

*Corticosteroids:* Increased risk of gastro-intestinal bleeding (see section 4.4-special warning and precaution for use).

*Anticoagulants:* NSAIDs may enhance the effects of anticoagulants, such as warfarin see section 4.4 –Special warning and precautions for use).

*Quinoline antibiotics:* Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.

*Tacrolimus:* Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.

#### **4.6 Pregnancy and lactation**

*Pregnancy:*

Congenital abnormalities have been reported in association with NSAIDs administration in man; however, these are low in frequency and do not appear to follow any discernible pattern.

In view of the known effects of NSAIDs on the foetal cardiovascular system (risk of the closure of the ductus arteriosus), use in the last trimester of pregnancy is contraindicated.

The onset of labour may be delayed and the duration increased with an increase bleeding tendency in both mother and child (See section 4.3 Contraindications).

NSAIDs should not be used during the first two trimesters of pregnancy or labour unless the potential benefit to the patients outweigh the potential risk to the foetus.

*Lactation:*

In limited studies so far available, NSAIDs can appear in breast milk in very low concentrations. NSAIDs should, if possible, be avoided when breastfeeding.

See section 4.4 Special warnings and precautions for use, regarding female fertility.

#### 4.7 **Effects on ability to drive and use machines**

Dizziness, drowsiness, visual disturbances or headaches are possible undesirable effects after taking NSAIDs, if affected, patients should not drive or operate machinery.

#### 4.8 **Undesirable effects**

*Gastro-intestinal:* The most commonly observed adverse events are gastro-intestinal in nature. Peptic ulcer, perforation or GI bleeding, sometimes fatal, particularly in the elderly may occur (see section 4.4). Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease (See section 4.4-Special warning and precaution for use) have been reported following administration. Although diarrhoea may occur soon after starting treatment, it may also occur after several months of continuous use. The diarrhoea has been investigated in some patients who have continued this drug in spite of its continued presence. These patients were found to have associated proctocolitis. If diarrhoea does develop the drug should be withdrawn immediately and this patient should not receive mefenamic acid again. Pancreatitis has been reported. Less frequently, gastritis has been observed.

A positive reaction in certain tests for bile in the urine of patients receiving mefenamic acid has been demonstrated to be due to the presence of the drug and its metabolites and not to the presence of bile.

*Hypersensitivity:* Hypersensitivity reactions have been reported following treatment with NSAIDs. These may consist of (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritis, urticaria, purpura, angioedema and, less commonly, bullous dermatoses (including epidermal necrolysis and erythema multiforme) The occurrence of a rash is a definite indication to withdraw medication.

*Cardiovascular:* Oedema has been reported in association with NSAID treatment. Hypotension and palpitations have been reported rarely.

Other adverse events reported less commonly include:

*Renal:* As with other prostaglandin inhibitors allergic glomerulonephritis has occurred occasionally. There have also been reports of acute interstitial nephritis with haematuria and proteinuria and occasionally nephrotic syndrome.

Non-oliguric renal failure has been reported on a few occasions in elderly patients with dehydration usually from diarrhoea. Toxicity has been seen in patients with pre-renal condition leading to a reduction in renal blood flow or blood volume. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, and liver dysfunction, those taking diuretics and elderly. The drug should not be administered to patients with significantly impaired renal function. It has been suggested that the recovery is more rapid and complete with other forms of analgesic induced renal impairment, with discontinuation of NSAID therapy being typically followed by recovery to the pre-treatment state.

*Hepatic:* Borderline elevations of one or more liver function tests may occur in some patients receiving mefenamic acid therapy. A patient with symptoms and/or signs suggesting liver dysfunction or in whom an abnormal liver test has occurred should have their therapy discontinued. Patients on prolonged therapy should be kept under surveillance with particular attention to liver dysfunction. Hepatitis and jaundice have been reported with NSAID therapy.

*Neurological & special senses:* Visual disturbances, optic neuritis, headaches, paraesthesia, reports of aseptic meningitis (especially in patients with auto-immune disorders, such as systemic lupus erythematosus mixed connective tissue disease), with symptoms such as stiffneck, headache, nausea, vomiting, fever or disorientation (see section 4.4) depression, confusion, hallucinations, tinnitus, vertigo, dizziness, malaise, fatigue and drowsiness.

*Haematological:* Thrombocytopenia, neutropenia, aplastic anaemia has been reported. In some cases reversible haemolytic anaemia has occurred.

Temporary lowering of the white blood cell count, which may have been due to mefenamic acid has been reported. Rarely eosinophilia, agranulocytosis and pancytopenia has been reported. Blood



studies should therefore be carried out during long term administration and the appearance of any dyscrasias is an indication to discontinue therapy.

*Dermatological:* Photosensitivity (see Hypersensitivity for other skin reactions).

Other adverse reactions: Glucose intolerance in diabetic patients has been reported rarely.

A positive reaction in certain tests for bile in the urine of patients receiving Mefenamic acid has been demonstrated to be due to the presence of drug and its metabolites and not to the presence of bile.

#### **4.9 Overdose**

##### *a) Symptoms*

Symptoms include headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, rarely diarrhoea, disorientation, epigastric pain, gastrointestinal bleeding disorientation excitation, coma, drowsiness, dizziness, tinnitus, fainting, occasionally convulsion. In cases of significant poisoning acute renal failure and liver damage are possible.

##### *b) Therapeutic measure*

Patients should be treated symptomatically as required.

Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life threatening overdose.

Good urine output should be ensured.

Renal and liver function should be closely monitored.

Patients should be observed for at least four hours after ingestion of potentially toxic amounts.

Frequent or prolonged convulsions should be treated with intravenous diazepam. Other measures may be indicated by the patient's clinical condition.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

M01 A G01 Anti-inflammatory and anti-rheumatic products, non-steroids, Fenamates.

Mefenamic acid belongs to the family of drugs called fenamates, which are aspirin-like drugs that are derivatives of N-phenylanthranilic acid. In tests of anti-inflammatory activity, mefenamic acid is about half as potent as phenylbutazone. Mefenamic acid has antipyretic and analgesic properties and displays a central as well as a peripheral action. Mefenamic acid appears to owe these properties to its capacity to inhibit cyclo-oxygenase.

#### **5.2 Pharmacokinetic properties**

Peak concentrations in plasma are reached in 2 to 4 hours and the half-life of the drug is also 2 to 4 hours.

In man, approximately 50% of a dose of mefenamic acid is excreted in the urine. Of this, approximately half is the conjugated 3-hydroxymethyl metabolite, a little less than half is the 3-carboxyl metabolite and its conjugates, and the remaining few percent is mostly conjugated mefenamic acid.

Twenty percent of the drug is recovered in the faeces, mainly as the unconjugated 3-carboxyl metabolite.

#### **5.3 Preclinical safety data**

Not available.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Lactose monohydrate  
Gelatin,  
Sodium starch glycollate,  
Sodium laurilsulfate.

Capsule shell excipients:  
Patent blue V (E131),  
Erythrosine (E127),  
Titanium dioxide (E171),  
Yellow iron oxide (E172),  
Gelatin.

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

3 years.

### **6.4 Special precautions for storage**

Store below 30°C.

### **6.5 Nature and contents of container**

1. Polypropylene tubes with low density polyethylene caps. High density polyethylene film may be used as packing material.
2. Snap-Safe Vials: Child resistant containers consisting of polypropylene tubes with high density polyethylene caps.

Pack sizes: 50, 84, 100, 250, 500 and 1000 capsules.

### **6.6 Special precautions for disposal**

Not applicable.

## **7 MARKETING AUTHORISATION HOLDER**

Pharmvit Limited  
Derby Road  
Greenford  
Middlesex UB6 8UJ

## **8 MARKETING AUTHORISATION NUMBER(S)**

PL 4556/0045

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

28/07/2006

## **10 DATE OF REVISION OF THE TEXT**

28/07/2006

**MEFENAMIC ACID 250MG CAPSULES**  
**PL 04556/0045**  
**PATIENT INFORMATION LEAFLET**

**PATIENT INFORMATION LEAFLET**

**MEFENAMIC ACID 250 mg CAPSULES**

THIS LEAFLET PROVIDES A SUMMARY OF THE INFORMATION AVAILABLE ON YOUR MEDICINE; PLEASE READ IT CAREFULLY BEFORE YOU START TO TAKE YOUR MEDICINE. IF YOU HAVE ANY QUESTIONS OR ARE NOT SURE OF ANYTHING ASK YOUR DOCTOR OR PHARMACIST.

**WHAT IS IN THIS MEDICINE?**

Mefenamic Acid capsules 250 mg is blue and brown in colour and printed with PV and M250. Each capsule contains 250 mg of mefenamic acid, the active ingredient.

The capsules also contain the inactive ingredients lactose monohydrate, gelatin, sodium starch glycollate and sodium laurilsulfate. The capsule shell contains gelatin and the colours patent blue (E131), erythrosine (E127), yellow iron oxide (E172) and titanium dioxide (E171).

Each capsule contains 450 micrograms of sodium.

Pack sizes: 50, 84,100,250,500 and 1000 capsules

**WHAT IS MEFENAMIC ACID?**

Mefenamic acid is one of a group of medicines called non-steroidal anti-inflammatory drugs. It causes a reduction in the levels of prostaglandins, substances believed to be responsible for causing pain and inflammation.

Manufacturer: Clonmel Healthcare Ltd. Waterford Road. Clonmel. Co Tipperary. Ireland.

M A Holder: Pharmvit Ltd. Unit 13 Metropolitan Centre, Derby Road Greenford Middx. UB6 8UJ.

**WHAT IS THIS MEDICINE FOR?**

Mefenamic acid is used for the relief of pain and discomfort caused by arthritis, muscular pain, headache, periods, toothache, and fever in children. It may also be used to relieve pain after operations or childbirth.

**WHAT DO YOU NEED TO KNOW BEFORE TAKING THIS MEDICINE?**

If the answer to any of the following questions is YES, **DO NOT** take this medicine without consulting your doctor.

- Have you had an allergic reaction (wheezing, skin rash, itchy or runny nose) after taking mefenamic acid, aspirin or any other medicine used to treat painful conditions?
- Are you allergic to any of the other ingredients? (See 'WHAT IS IN THIS MEDICINE?' above.)
- Are you pregnant, planning to become pregnant or breast-feeding?
- Do you have liver, kidney or heart trouble?
- Do you have high blood pressure?
- Do you suffer from epilepsy?

- Have you ever had stomach pains, felt like being sick or had heartburn after taking aspirin or any other medicine used to treat painful conditions?
- Do you suffer from asthma or other allergic disease?
- Are you presently suffering from dehydration?

If the answer to any of the following questions is YES, tell your doctor or pharmacist

Do not take Mefenamic Acid if you have, or have ever had, peptic ulceration (ulcer in your stomach or duodenum) or bleeding in your digestive tract.

*Mefenamic acid may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.*

If you have a urine test, tell the doctor that you are taking mefenamic acid because the medicine may affect the result.

As this medicine may make you feel dizzy or drowsy, you should not drive or operate machinery until you know how the drug affects you.

If you are elderly you should consult your doctor before taking this medicine.

#### **ARE YOU TAKING ANY OTHER MEDICINES?**

You should consult your doctor BEFORE taking any other medicines, particularly any of the following:

- Other non-steroidal anti-inflammatory drugs (e.g. ibuprofen).
- Medicines used to thin the blood (anticoagulants, e.g. warfarin).
- Diuretics (water tablets) and other drugs used to treat high blood pressure (e.g. frusemide and indapamide).
- Medicines used for heart trouble (e.g. digoxin).
- Lithium, a treatment for depression.
- Methotrexate, a drug used in cancer therapy.
- Ciclosporin, a drug used following organ transplants.
- Quinolone antibiotics, which are used to treat bacterial infections (e.g. ciprofloxacin).
- Mifepristone, a drug used for terminating pregnancy.
- Corticosteroids, which are used to treat allergic and inflammatory diseases and immune reactions (e.g. prednisolone).

#### **HOW MUCH OF THIS MEDICINE SHOULD YOU TAKE?**

You should take your medicine as directed by your doctor. The pharmacist's label should tell you how much to take and how often. If it does not or you are not sure ask your doctor or pharmacist. *The capsules should be swallowed with a drink of water. To be taken preferably with or after food.*

### **Adults**

The usual dose is 2 capsules taken three times daily.

*Dysmenorrhoea (painful periods):* Begin taking this medicine at the onset of period pain. Your doctor will advise you how long you should take this medicine for.

*Menorrhagia (heavy or prolonged periods):* Begin taking this medicine on the first day of excessive bleeding. Your doctor will advise you how long you should take this medicine for.

### **Elderly**

Your doctor will put you on the lowest effective dose, to minimise side effects. You should be under regular supervision by your doctor while taking this medicine.

- Mefenamic acid capsules are not suitable for children under 12 years.
- Swallow the capsules with a drink of water preferably with or after food.

### **WHAT IF YOU HAVE TAKEN TOO MANY CAPSULES?**

If you or anyone else has swallowed a lot of the capsules all together contact your nearest hospital casualty department or doctor immediately.

If you forget to take a dose, take it as soon as you remember, unless it is nearly time to take the next one. Never take two doses together. Then go on as before.

### **WHAT UNWANTED EFFECTS CAN THIS MEDICINE HAVE?**

If you suffer from any of the following at any time during your treatment STOP TAKING the medicine and *seek immediate medical help*:

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

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

- Indigestion or heartburn
- Abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

This medicine, like most other medicines, may cause side effects in some people.

If you experience any of the following **STOP** taking the capsules and tell your doctor **IMMEDIATELY**.

- Skin rashes or itching for the first time.
- Wheezing or shortness of breath.
- Persistent sore throat or high temperature.
- Yellowing of your skin or the whites of your eyes.
- Diarrhoea

You should tell your doctor **as soon as possible** if you notice any of the following side effects after taking this medicine:

- Blurred vision
- Pain in the eyes
- Sore mouth
- Puffiness of the face
- Hallucinations
- Your skin may become more sensitive to light
- Anaemia
- Bruising or bleeding easily

- Red urine
- Protein in the urine (your doctor may test for this from time to time)

The following side effects are often mild and may wear off after a few days' treatment. If they are severe or last more than a few days, tell your doctor.

- Stomach discomfort
- Nausea
- Indigestion
- Vomiting
- Headaches
- Feeling unwell
- A ringing in the ears
- Pins and needles

Other rare side effects include confusion, depression, dizziness, drowsiness, vertigo (spinning sensation) and severe skin disorders.

Mefenamic acid can reduce the number of certain types of blood cells, and therefore your doctor may wish to perform regular blood tests while you are taking this medicine. If you have a blood test, for any other reason, remember to tell the doctor that you are taking mefenamic acid.

If you experience any of the above or are concerned about anything or you notice anything unusual contact your doctor.

#### **HOW SHOULD YOU STORE THIS MEDICINE?**

This medicine should not be used after the expiry date stated on the pack. Mefenamic acid capsules should be stored below 30°C.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

REMEMBER: This medicine has been prescribed for you. Do not give it to anybody else even if their symptoms appear to be the same as yours, since it may be harmful to them.

PL 4556/0045

POM

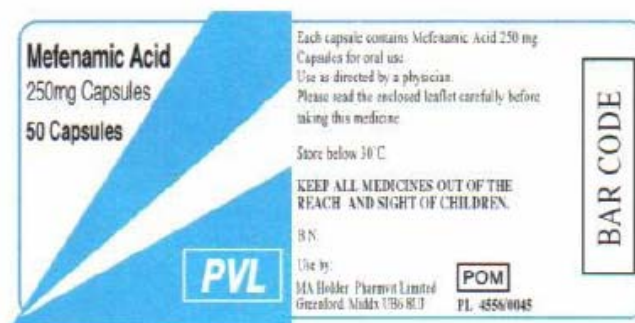
Pharmvit Ltd

Last revision date: August 2005

**MEFENAMIC ACID 250MG CAPSULES  
PL 04556/0045**

**LABELLING**

Colour Mock-up label for Mefenamic Acid 250 mg Capsule for pack size of 50



Colour Mock-up label for Mefenamic Acid 250 mg Capsule for pack sizes 84, 100, 250, 500, 1000.  
Label text will remain the same for all the pack sizes.

