Ponalgic® 250mg Hard Capsules and Ponalgic® Forte 500mg Film-Coated Tablets

(Mefenamic Acid)

Read all 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 nurse.
-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 nurse. This includes any possible side effects not listed in this leaflet.*See section 4.*

What is in this leaflet:

1. What Ponalgic 250mg hard capsules and Ponalgic Forte 500mg film-coated tablets are and what they are used for
2. What you need to know before you take Ponalgic
3. How to take Ponalgic
4. Possible side effects
5. How to store Ponalgic
6. Contents of the pack and other information

1.What Ponalgic 250mg hard capsules and Ponalgic Forte 500mg film-coated tablets are and what they are used for

Ponalgic 250mg Hard Capsules contain 250mg Mefenamic Acid, the active ingredient.
Ponalgic Forte 500mg Film-Coated Tablets contain 500mg Mefenamic Acid.

Mefenamic acid belongs to a group of medicines called Non-Steroidal Anti-inflammatory (NSAID) agents.

Ponalgic 250mg Hard Capsules and Ponalgic Forte 500mg Film-Coated Tablets may be used

- for relief of mild to moderate pain associated with rheumatic muscular or arthritic disorders, including rheumatoid arthritis, and osteoarthritis
- for relief of mild to moderate pain due to an injury, headache, toothache, or following an operation or after childbirth
- to relieve the type of period pains for which no cause can be shown
- in the management of excessively heavy periods(where the irregular excessive bleeding may not have an obvious cause)

2. What you need to know before you take Ponalgic

Do not take Ponalgic if:

- you have or ever had an ulcer or inflammation in your stomach or intestine
- you have had a history of two or more distinct episodes of bleeding from repeated peptic ulceration
- you have had a history of stomach or intestinalbleeding/perforation, related to previous NSAIDs (drugs used to reduce pain) therapy

•you are taking other non-steroidal anti-inflammatory medicines(this includes aspirin, ibuprofen and medicines called cox 2 inhibitors)
• you are pregnant or if you are breast-feeding
• you have kidney, liver or heart problems
• you are allergic to mefenamic acid, aspirin, or any other non-steroidal anti-inflammatory drugs (for example if you ever had a bad reaction such as a skin rash, an itchy or runny nose or shortness of breath after taking one of these medicines)
•you sufferfrom severe heart failure.
• you have had a reaction to any of the ingredients in this medicine listed in section 6.

Ponlagic should not to be used in children

If any of these apply to you, tell your doctor and do not take Ponalgic. Your doctor will decide whether this medicine is suitable for you.

Warnings and Precautions
Talk to your doctor or nurse before taking Ponlagic if
• If you are dehydrated (for example you have been losing fluid through vomiting, diarrhoea or passing too much or too little urine)
• you are suffering from excessive loss of body fluid
• you have a connective tissue disorder such as SLE (Systemic Lupus Erythematosus)
•you have asthma, a history of asthma or other allergic disease
•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 or if you drink alcohol) you should discuss this treatment with your doctor or pharmacist.
• you ever had a brain haemorrhage or any form of bleeding disorder
• you have had fits (epilepsy)
• you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
• you are elderly, and have a history of bleeding or perforation after taking such medicines, please inform your doctor immediately if youexperience any unusual abdominal symptoms in the initial stages of treatment.

Medicines such as Ponalgic 250mg Hard Capsules and Ponalgic Forte 500mg Film-CoatedTablets may be associated with a small increased risk of heart attack (“myocardial infarction”) orstroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed therecommended dose or duration of treatment.
Serious skin reactions may occur very rarely with nonsteroidal anti-inflammatory medicines including mefenamic acid (the ingredient of ponalgic). The reactions include exfoliative dermatitis (intense reddening of skin, with skin peeling off in scales or layers), Stevens-Johnson syndrome (symptoms are a rash, blistering or peeling of the skin, mouth, eyes or genitals) or toxic epidermal necrolysis (a disease with blistering and peeling of the top layer of skin. If they occur they tend to occur in the early part of therapy (e.g. first month of treatment with ponalgic). At the first appearance of any of the skin reactions, therapy with ponalgic should be immediately discontinued and talk to your doctor.

Long term use of any type of painkiller for headaches can make them worse. Please contact your doctor immediately if you experience frequent daily headaches with the use of headache medications.

Other medicines and Ponalgic:
Tell your doctor or nurse if you are taking or have recently taken any other medicines.
In particular tell your doctor if you are taking:

- anticoagulant e.g. warfarin or heparin (to reduce the clotting power of your blood)
- medicines for high bloodpressure;
- diuretic(to help you pass more water);
- cardiac glycosides, e.g. digoxin (fora heart problem);
- lithium (for depression);
- methotrexate (to damage unwanted cells);
- cyclosporine (to suppress the body's immune response);
- corticosteroids (for example forasthma or other inflammatory conditions);
- aminoglycoside antibiotic (for an infection);
- probenecid (e.g. for gout);
- tablets for diabetes;
- other non-steroidal anti-inflammatorymedicine (e.g. for pain or arthritis);
- oral medications such as sulfonylurea class of medicines (e.g. chlorpropamide) used for the treatment of diabetes mellitus
- mifepristone (used for termination of pregnancy
- anti-platelet agents (e.g. aspirin)
- quinolone antibiotic (for an infection e.g. ciprofloxacin,norfloxacin and nalidixic acid);
- zidovudine (an anti-viral drug);
- tacrolimus (used to suppress the body's immune system,e.g. following transplants or in diseases such as psoriasis and rheumatoid arthritis).

If you are unsure about interactions with any other medicines, talk to your doctor or pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for yourself, including herbal and homeopathic remedies.

Pregnancy and breastfeeding

- you should not take this medicine if you are pregnant

• you should not take this medicine while breast-feeding

Driving and using machines
You should not drive or operate machines if you feel dizziness, drowsiness, tired or have changes in your vision after taking this medication.

3. How to take Ponalgic
• Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
• Swallow the capsules or tablets whole with a drink of water. Do not chew them or break them
• If you forget to take a dose, just carry on with the next dose whenever it is due. Do not take an extra one to make up.

Dosage for Adults
Ponalgic 250mg Hard Capsules:
The recommended dose is 2 capsules three times daily (total daily dose 1,500mg).

Ponalgic Forte 500mg Film-Coated Tablets:
The recommended dose is 1 tablet three times daily (total daily dose 1,500mg).

Older people:
The dosage should be kept as low as possible under medical supervision.

Use in Children: Ponalgic 250mg Hard Capsules and Ponalgic Forte 500mg Film-Coated Tablets are not for use in children.

If you take more Ponalgic than you should
If you take too many capsules or tablets, or if you think that a child has swallowed some of them, contact your doctor or the nearest hospital immediately. Bring the capsules or tablets with you, if possible in their container.

4. Possible side effects:
Like any medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor immediately and stop taking Ponalgic if you experience any of the following symptoms after taking this medicine:
• any sign of bleeding in the stomach or intestines, such as passing black or bloodstained stools or vomiting blood
• sudden wheeziness, difficulty in breathing, fever, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)
• a rash, blistering or peeling of the skin, mouth, eyes or genitals
• yellowing of the skin and the whites of your eyes (jaundice) which may be a sign of hepatitis or other liver problems

The commonly† reported side effects with Ponlagic are:
- Diarrhoea, if diarrhoea persists contact your doctor immediately
- Feeling sick (nausea), vomiting, loss of appetite

† Side effects affecting up to 1 in 10 people

The following side effects have been reported since the marketing of Ponlagic but the frequency for them to occur is not known (frequency cannot be estimated from the available data):
<u>Effects on blood:</u>
- Abnormalities in blood affecting cells in the blood and decrease of haemoglobin in blood (anaemia) causing pallor and tiredness. These effects may result in unusual bruising or bleeding or increased risk of infection

<u>Effects on your nervous system:</u>
- Dizziness
- Vertigo (a spinning sensation)
- Headache
- Changes in sleep patterns
- Depression
- Hallucinations

- Nervousness

Effects on your eyes and ears:
- Hearing impairment, ringing in ears, pain in ears
- Swollen eyes, blurred vision, eye irritation and loss of colour vision

Effects on heart, chest and circulation:
- Fast or pounding heartbeat, breathlessness, high blood pressure, swollen ankles and/or feet (oedema)

Medicines such as Ponalgic may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Effects on the stomach and digestive system:
- Constipation,
- Inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, taste changes,
- Lower gut disorders (including inflammation of the colon, or worsening of ulcerative colitis or Crohn's disease).

Elderly patients are more susceptible to stomach or intestinal bleeding which could be more serious as compared to those occurring in younger patients. Stop taking this medicine and see your doctor immediately if you experience any symptoms of stomach or intestinal bleeding; passing black or bloodstained stools or vomiting blood.

Effects on the liver:
- Severe liver disorders including liver failure

Effects on kidneys:
- Kidney inflammation,
- kidney failure or kidney damage.

If you notice any change in your urine output or appearance, possibly accompanied by kidney pain, or pain in your abdomen or back contact your doctor

Effects on skin:
- Rashes, itching, redness, tenderness, thickening or scaling of skin,
- Loosening or splitting of fingernails
- Hair loss
- Increased sensitivity of the skin to sunlight

Other side effects that have been reported include:
- Inflammation of the pancreas (which may lead to severe pain in the upper abdomen or back)
- Facial swelling
- inflammation of the lining of the brain (meningitis)
- Stroke
- Throat disorders

- Confusion
- Malaise (general feeling of discomfort)
- Inflammation of the nerves in the eye
- Fixed drug eruption

If you are receiving a long course of treatment with mefenamic acid, your doctor will arrange to see you at times to check that your medicine is suiting you. Please make sure to keep these appointments.

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 or nurse.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ponalgic:

Keep this medicine out of the sight and reach of children.
Do not use the capsules or tablets after the expiry date printed on the container.
Ponalgic 250mg Hard Capsules and Ponalgic Forte 500mg Film-Coated Tablets should be stored below 25°C and protected 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.

6. Contents of the pack and other information:

What Ponalgic contains:

Ponalgic 250mg Hard Capsules contain 250mg Mefenamic Acid, the active ingredient.
The capsules also contain the following inactive ingredients: maize starch, lactose monohydrate, magnesium stearate, sodium starch glycollate and sodium lauryl sulphate. The capsule shells are made of gelatin and also contain the colourants titanium dioxide E171, Quinoline Yellow E104, erythrosine

E127, Patent Blue E131, Sodium Lauryl sulfate, water and black iron oxide E172. The hard gelatin capsules are coloured blue and yellow.
Ponalgic 250mg Hard Capsules are available in securitainers of 50, 100, 168, or 500.

Ponalgic Forte 500mg Film-Coated Tablets contain 500mg Mefenamic Acid.
The tablet cores also contain the following inactive ingredients: microcrystalline cellulose, sodium starch glycollate, gelatin, magnesium stearate, croscarmellose sodium and colloidal anhydrous silica. The tablet coating contains lactose monohydrate, hydroxypropylmethylcellulose, polyethylene glycol and the colourants titanium dioxide E171, iron oxide yellow E172 and quinoline yellow E104. They are capsule shaped, yellow coloured film-coated tablets, with 'a' logo and 'MA500' on one side.

Ponalgic Forte 500mg Film-Coated Tablets are available in securitainers of 50, 100 or 168.

Manufacturer and holder of Product Authorization:
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