

PONTACID FORTE TABLET

Mefenamic Acid (500mg)

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What PONTACID is used for

PONTACID is used in the treatment of menstrual cramps (period pain) and heavy menstrual periods.

It is also used to relieve mild to moderate pain such as dental pain and soft tissue pain, osteoarthritis (degenerative joint disease), rheumatoid arthritis (systemic inflammatory disorder that affects joints).

How PONTACID works

PONTACID contains the active ingredient mefenamic acid.

PONTACID belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (or NSAID) which relieve pain, inflammation and fever.

Before you use PONTACID

- When you must not use it

Do not take this medicine if you have an allergy to:

- mefenamic acid, the active ingredient
- any of the other ingredients listed at the end of this leaflet

Do not take PONTACID if:

- you had diarrhoea with this medicine in the past.

Diarrhoea may recur if you take PONTACID again.

- you have or have had ulceration or inflammation of the stomach or intestinal.
- you have impaired kidney function.
- you have had bronchospasm (constriction of your airway), rhinitis (Inflammation of the nasal mucous membrane), urticaria (itching or hives) and the symptoms become worsened caused by Aspirin or NSAIDs.

Do not give PONTACID to a child under 14 years. The safety and effectiveness of PONTACID in children have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart problem or stroke
- a tendency to bleed or other blood problems
- may cause severe skin reactions, e.g., exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms may include skin rash, blisters and peel off. These could

be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

- kidney disease
- liver disease
- high blood pressure
- ulceration, bleeding and perforation of the stomach and intestinal
- suffering from dyspepsia (discomfort at the epigastric region due to digestion problem).

Tell your doctor if you are pregnant, plan to become pregnant or breastfeeding. Your doctor will discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking PONTACID Forte Tablet.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and PONTACID may interfere with each other. This includes warfarin, a medicine used to stop blood clots. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use PONTACID

Follow all directions given to you by your doctor or pharmacist carefully. They may

differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

- How much to use

The dosage of PONTACID depends on the condition it is being used to treat.

Take PONTACID as directed by your doctor or pharmacist.

The usual starting dose of PONTACID is 500mg, followed by 250mg every 6 hours as needed.

Adults: Initially 500 mg followed by 250 mg 6 hourly as required.

Dysmenorrhoea: 500 mg three times daily with meals from the onset of pain and continued for the usual duration of pain.

Menorrhagia: 500 mg three times daily with meals from the onset of menses and continued according to the judgement of the physician.

Therapy should not be continued for more than 7 days except on the advice of a physician.

Other indications: Short term relief of mild to moderate pain such as dental pain and soft tissue pain - 500 mg three times daily.

After assessing the risk/ benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.

Do not take more tablets that your doctor has recommended.

Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to take it

Do not use PONTACID for longer than your doctor says.

Depending on your condition, you may need PONTACID for a few days, a few weeks or for longer periods.

For menstrual cramps (period pain), PONTACID is usually taken during each period as soon as the cramps begin and continued for a few days until the pain goes away.

For heavy menstrual periods, PONTACID is taken from the beginning of the period and continued according to your doctor's advice. You should not take PONTACID for more than 7 days unless recommended by your doctor.

If you are not sure how long to take PONTACID, talk to your doctor or pharmacist.

- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much PONTACID.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Taking too much PONTACID may cause stomach and intestinal discomfort and diarrhoea to muscle twitching, fit and coma.

While you are using it

- Things you must do

If you become pregnant while taking PONTACID tell your doctor immediately.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking PONTACID.

Tell all of the doctors, dentists, and pharmacists that are treating you that you are taking PONTACID.

If you suffer from skin rash and blisters during your treatment, inform your doctor immediately.

- Things you must not do

Do not give PONTACID to anyone else, even if they have the same condition as you.

Do not use PONTACID to treat any other complaints unless your doctor tells you to.

- Things to be careful of

Be careful driving or operating machinery until you know how PONTACID affects you.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Eye irritation, ear pain, perspiration, mild hepatic toxicity and increased need for insulin in a diabetic have been reported. There have been rare reports of palpitation, dyspnoea and reversible loss of colour vision.

Gastrointestinal (Stomach disorder): Frequently, gastrointestinal tract; diarrhoea, nausea with or without vomiting, other gastrointestinal symptoms, and abdominal pain. Diarrhoea was of sufficient severity to require discontinuation of the medication. The occurrence of diarrhoea is usually dose related, generally subsides on reduction of dosage and rapidly disappears on termination of therapy. Less frequently, anorexia, pyrosis (heartburn), flatulence and constipation. Gastrointestinal ulceration with or without haemorrhage (bleeding).

Haematopoietic (Blood disorder): Auto-immune haemolytic anaemia (a disease in which the body immune system attacks the red blood cells) associated with a continuous administration of mefenamic acid for 12 months or longer. The process is reversible upon termination of mefenamic acid administration. Decreases in haematocrit (proportion of red blood cells in total blood volume) and is primarily seen in those who

have received prolonged therapy. Reduced white blood cell count, decrease in platelet count (which causes bleeding), and bone marrow abnormalities have also been reported on occasion.

Nervous system: Drowsiness, dizziness, nervousness, headache, blurred vision, and insomnia have occurred.

Integumentary: Urticaria/hives (red bumps on skin), rash, and facial swelling have been reported.

Renal (Kidney disorder): As with others NSAIDs, renal failure including papillary necrosis has been reported. In elderly patients renal failure has occurred after taking mefenamic acid for 2 to 6 weeks. The renal damage may not be completely reversible.

Haematuria (blood in urine) and dysuria (painful urination) have also been reported with mefenamic acid.

Skin rash sometimes with blisters.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of PONTACID

- Storage

Keep your medicine in the original container. If you take it

out of its original container it may not keep well.

Keep your medicine in a place where the temperature stays below 30°C. Protect from light.

Do not store PONTACID or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

- Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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.

Product description

- What it looks like

PONTACID FORTE TABLET 500MG

- A blue, oblong, 17mm indiameter tablet with marking 'dp 500' on one side.

- Ingredients

Active ingredient:

- Mefenamic Acid

Inactive ingredients:

- Polyvinylpyrrolidone (PVP)
- Cornstarch
- Brilliant blue
- Lactose
- Talc
- Magnesium stearate

- Sodium starch Glycolate (Promigel)
- Silicon Dioxide (Aerosil)
- Tween 80

- MAL numbers

MAL19890082AZ

**Product Registration Holder
& Manufacturer**

Duopharma (M) Sdn. Bhd.
Lot. 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia

Serial Number:

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