

PONSTAN[®] TABLET

Mefenamic Acid (500 mg)

PLD Title	: Mefenamic Acid (PONSTAN)
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What Ponstan is used for

Ponstan is used to relieve:

- Pain due to rheumatoid arthritis including Still's Disease,
- Pain due to osteoarthritis,
- Muscle pain,
- Trauma-related pain,
- Pain after injury,
- Toothaches,
- Headaches,
- Pain following an operation,
- Pain after childbirth,
- Painful menstruation (dysmenorrhea),
- Fever in children over 6 months of age.
- It is used to treat pre-menstrual syndrome and also abnormally heavy bleeding due to dysfunctional causes or the presence of an intrauterine device (IUD)

How Ponstan works

Ponstan contains the active substance mefenamic acid which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines reduce pain (analgesic) and swelling, (anti-inflammatory) and brings down fever (antipyretic)

Before you use Ponstan

- When you must not use it

Do not take Ponstan if:

- you are allergic (hypersensitive) to mefenamic acid or any of the

other ingredients of this medicine;

- you show any signs of allergy (such as asthma, hay fever or hives) to aspirin 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 currently have a stomach ulcer or bleeding;
- you suffer from chronic inflammation of either the upper or lower gastrointestinal tract;
- you have severe kidney problems;
- you have severe problems with your liver;
- you suffer from severe heart failure;
- you encounter pain before undergoing a coronary artery bypass graft (CABG) (type of surgery that improves blood flow to the heart). Ponstan should not be used to treat pain in the setting of the CABG.

Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking any medicine. You should inform your doctor if you are planning to become pregnant or if you have problem becoming pregnant. Ponstan should be used only if the potential benefits to the mother justify the possible risks to the fetus. Ponstan should not be taken especially during the last trimester of pregnancy. If taken during second or third trimester, pregnant women should be monitored for amniotic fluid volume.

Do not take Ponstan if you are breast feeding.

- Before you start to use it

Talk to your doctor before taking Ponstan if:

- you have had ulcer or some other problem affecting your stomach, or intestines;
- you have any known cardiovascular disease or risk factors for getting it;
- you have high blood pressure;
- you have swelling in different areas of the body due to fluid accumulation;
- you suffer from any blood abnormality.

- Taking other medicines

Tell your doctor if you are taking any of the following:

- anticoagulants (medicines used to make the blood thin for preventing blood clots);
- diuretics (water tablets) and antihypertensives (medicines for the treatment of high blood pressure), such as angiotensin-converting enzyme (ACE) inhibitors, angiotensin II antagonists and beta blockers;
- corticosteroids (medicines used to treat asthma and various inflammatory conditions);
- cyclosporine or tacrolimus (medicines to suppress the body's immune system especially following transplantation);
- medicines used to treat high blood sugar;
- lithium (medicine used to treat bipolar disorder and depression);
- methotrexate (medicines used to treat cancer);
- aspirin or any other NSAIDs including cyclo-oxygenase-2 (COX-2)-specific inhibitors.

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

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How to use Ponstan

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Ponstan should be taken with or after food.

Adults: The usual dose is one tablet (500 mg) three times each day.

For excessively heavy menses, start taking your medicine on the first day of excessive bleeding and continue as directed by your doctor.

For menstrual pains, start taking your medicine when you first notice the pain and continue as directed by your doctor.

For Still's disease or fever in infants and children over 6 months to 14 years: 19.5 mg/kg to 25 mg/kg of body weight daily in divided doses three times a day.

As a general principle, the smallest effective dose should be used.

Children and adolescents:

Ponstan is reported to be effective for fever in infants and children over 6 months of age and for pain in adolescents over 14 years of age.

Elderly: Ponstan should be used with caution in individuals suffering from kidney problems.

Elderly or debilitated patients seem unable to tolerate ulceration or bleeding as well as some other individuals; most spontaneous reports of fatal gastrointestinal events are in this patient population.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Ponstan for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause seizures (fits), kidney failure, coma (deep state of unconsciousness), confusion, vertigo (feeling dizzy or spinning) and hallucination (perceiving things that do not exist outside the mind) and may lead to death also.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Inform all the doctors, dentists and pharmacists treating you that you are taking Ponstan.

Inform your doctor immediately if you become pregnant while taking this medication.

Inform your doctor immediately if you suffer from any of the following at any time during your treatment:

- diarrhoea;
- passing blood in your stools, black tarry stools, vomit any blood or dark particles that look like coffee grounds;
- indigestion or heart burn;
- stomach pain or other abnormal stomach symptoms;
- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; asthma or worsening of existing asthma, skin rash or hives);
- blistering of the skin, mouth, eyes and genitals;
- swelling in the feet, hands or ankles.

If you need to have any medical tests while you are taking Ponstan, inform your doctor as Ponstan may affect the results of some tests.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

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

- Things to be careful of

Driving and using machines

The effect of mefenamic acid on the ability to drive and use machines has not been evaluated.

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Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Frequent side effects: Diarrhoea, stomach pain, nausea with or without vomiting.

Other side effects include:

- Aplastic anemia (a disorder in which the bone marrow greatly decreases or produces insufficient amount of blood cells), autoimmune hemolytic anemia (a rare disease in which the body produces antibodies to destroy red blood cells)
- Blood disorders including decrease in blood cells (leukopenia, pancytopenia, agranulocytosis), increase in certain type of blood cells (eosinophilia), clotting disorders
- Allergic reactions
- Worsening blood sugar levels in diabetic individuals, low sodium in blood, fluid retention
- Inflammation of the layer covering the brain (aseptic meningitis), blurred vision, fits, dizziness, drowsiness, headache, sleeplessness
- Eye irritation, reversible loss of color vision
- Ear pain
- Fast or irregular heartbeats
- Low or high blood pressure
- Difficulty in breathing
- Skin and subcutaneous disorders like swelling of face, itching, rash, severe peeling of skin (toxic epidermal necrolysis) and Stevens-Johnson syndrome, DRESS syndrome which is a drug reaction with rash, fever, organ injury and increase in certain type of blood cells (eosinophilia), sweating, allergy and scaling of skin

- Change in the amount or frequency of urine passed, burning feeling when passing urine or blood in urine, kidney failure
- Generalized swelling
- Abnormal liver function tests, passing blood in urine
- Condition of having abnormally low body temperature in children.

If you are elderly (over 65 years of age), you may have an increased chance of experiencing side effects.

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

Storage and Disposal of Ponstan

- Storage

Keep out of the reach and sight of children.

Store below 30°C

- Disposal

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

Ponstan tablets are available as elliptical, smooth, yellow film-coated tablets, embossed with 'P-D' logo on one side and bisected line on the other side. They are packed in blister packs of 10x50.

- Ingredients

Active ingredient(s)
Mefenamic acid

Inactive ingredients

Tablet: Corn starch pre-gelatinized, methyl cellulose, sodium lauryl sulphate, microcrystalline cellulose, corn starch, silicon dioxide colloidal, magnesium stearate, purified water.

Film Coating: HPMC 2910, HPMC 15cps, PEG 8000, Polysorbate 80, Saccharin sodium, Vanillin, Opaspray Yellow K-1-F-6105, Purified water.

Polishing: Wax Candelilla FCC Powder.

- MAL number:

Ponstan Tablet:
MAL19990598ASZ

Manufacturer

PT Pfizer Indonesia
Jakarta, Indonesia

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
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