

Mefenamic Acid

Ponstan® SF 250
250 mg Capsule

1.0 NAME OF THE PRODUCT

Mefenamic acid

2.0 DESCRIPTION OF THE PRODUCT

Mefenamic acid (Ponstan® SF 250) is available in hard gelatin capsule with scarlet opaque body imprinted with “Ponstan SF 250” in white and scarlet opaque cap imprinted with “SF” in white, containing white to slightly off-white powder. It is in blister of 10's in boxes of 200's.

3.0 WHAT IS IN THE MEDICINE?

Mefenamic acid (Ponstan® SF 250) is a non-steroidal anti-inflammatory drug (NSAID) used to relieve pain (analgesic) and swelling (anti-inflammatory). Each capsule contains 250 mg of Mefenamic acid.

4.0 STRENGTH OF THE MEDICINE

250 mg

5.0 WHAT IS THIS MEDICINE USED FOR?

Mefenamic acid (Ponstan® SF 250) is used to relieve various types of pain such as:

- headache
- body aches (rheumatoid arthritis [including Still's Disease]), osteoarthritis
- muscle and joint pains
- toothache
- sprains
- painful menstruation (dysmenorrhea)
- trauma-related pains

6.0 HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Undesirable effects may be minimized by using the minimum effective dose for the shortest duration necessary to control symptoms.

For adults and children over 14 years old, take one to two capsules initially, then one capsule three times a day, as needed, preferably taken with food.

7.0 WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

Ask your doctor before using this product if you:

- are allergic to Mefenamic Acid or any components of this product such as lactose, gelatin, sodium lauryl sulfate, purified water, corn starch, corn starch pregelatinized, methyl cellulose, microcrystalline cellulose, silicon dioxide, magnesium stearate, polyethylene glycol, polysorbate 80, saccharin sodium, vanillin, opaspray yellow, wax candelilla FCC powder, veegum, povidone, sodium hydroxide, glucono delta lactone, hydrochloric acid, sorbitol solution, sodium benzoate, sodium carboxymethylcellulose granulated sugar, artificial banana flavor, anise mint flavor, alcohol and chocolate flavor
- are allergic to other NSAIDs or aspirin

- have previous or active peptic ulcer or chronic gastrointestinal tract inflammation
- have liver disease or kidney disease
- have heart disease
- have hyperacidity
- have history of asthma or develop asthma attacks due to other medicines

8.0 CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

Mefenamic Acid (Ponstan® SF 250) should not be taken continuously beyond seven days except on the advice of the doctor. Taking NSAIDs for very long periods of time or in very high doses increases the risk of stomach irritation, bleeding, as well as other side effects and should be done only under medical supervision.

Consult your doctor if you:

- develop any signs and/or symptoms of serious cardiovascular toxicity
- have high blood pressure
- have diarrhea or serious gastrointestinal side effects (inflammation, bleeding, ulceration, perforation)
- develop skin rash, mucosal lesions, or any other sign of hypersensitivity
- are taking other medications
- are having difficulties conceiving or undergoing investigation of infertility
- are pregnant or nursing a baby

9.0 UNDESIRABLE EFFECTS OF THIS MEDICINE

Stop taking Mefenamic acid immediately if the following potential side effects occur:

- loose bowel movement, nausea with or without vomiting, upset stomach, peptic ulcer, gastrointestinal tract inflammatory or bleeding, mild liver toxicity or any other stomach/liver problems
- blurred vision, nervousness, dizziness, drowsiness, insomnia, headache, aseptic meningitis
- eye irritation, loss of color vision
- skin reactions: rash or skin itching, excessive perspiration, edema, drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), and generalized bullous fixed drug eruption (GBFDE)
- ear pain
- asthma, difficulty in breathing
- cardiovascular events (irregular heartbeat, high/low blood pressure)
- blood problems
- kidney and urinary problems including related test results such as urobilinogen urine (false-positive), liver function test abnormal
- abnormally low body temperature in children

Consult your doctor if any of these side effects occur.

Elderly individuals are more prone to side effects, therefore, report all side effects to your doctor immediately.

10.0 WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

Mefenamic Acid (Ponstan® SF 250) may interact with the following medications:

- Antiplatelet or Acetylsalicylic acid (e.g. Aspirin)

- Other nonsteroidal anti-inflammatory drugs
- Corticosteroids
- Anti-coagulants
- Diuretics or other anti-hypertensives
- Hypoglycemic agents
- Methotrexate
- Lithium
- Tacrolimus
- Cyclosporine

If you are taking or about to take any of the above medications, consult your doctor first before using mefenamic acid.

11.0 WHAT SHOULD YOU DO IF YOU MISS A DOSE?

Not applicable.

12.0 SIGNS AND SYMPTOMS OF OVERDOSE

You may experience seizures, acute renal failure, coma, confusional state, dizziness, and hallucination.

13.0 WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

In case of accidental overdosage, call for emergency help immediately.

Patients should be managed by symptomatic and supportive care following an overdose. There are no specific antidotes.

14.0 HOW SHOULD YOU KEEP THIS MEDICINE?

Store at temperatures not exceeding 30°C.

15.0 WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Consult your doctor if:

- before using this product, if you have any conditions mentioned in section **7.0 When should you not take this medicine?** and section **8.0 Care that should be taken when taking this medicine.**
- you experience any of the side effects mentioned in section **9.0 Undesirable effects of this medicine.**
- you are taking or about to take any of the medications mentioned in section **10.0 What other medicine or food should be avoided while taking this medicine?**
- you experience an overdosage.
- you have any questions about using this product.

16.0 FDA REGISTRATION NUMBER

Mefenamic acid (Ponstan® SF) 250 mg capsule: DRP-2074

17.0 DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Mefenamic acid (Ponstan® SF) 250 mg Capsule: 20 August 1964

Keep out of reach of children.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Seek medical attention immediately at the first sign of any adverse drug reaction.

Manufactured by:

Interphil Laboratories, Inc.
Canlubang Industrial Estate
Bo. Pittland, Cabuyao, Laguna

Marketing Authorization Holder:

Pfizer, Inc.
19F-20F, 8 Rockwell Building, Hidalgo Drive,
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Under authority of PFIZER, INC., New York, N.Y., USA

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