PART III: CONSUMER INFORMATION

PONSTAN®

(Mefenamic Acid)

Capsule 250 mg B.P.

Read this information each time you refill your prescription in case new information has been added. This leaflet is part III of three-part ``Product Monograph`` published when PONSTAN® was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about PONSTAN®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Your health care provider has prescribed PONSTAN® for you for one or more of the following medical conditions:

- discomfort caused by muscular aches
- headache
- primary dysmenorrhea
- dental pain.

What it does:

PONSTAN® (Mefenamic acid) as a nonsteroidal anti-inflammatory drug (NSAID), can reduce the chemicals produced by your body which cause pain and swelling. PONSTAN® has demonstrated analgesic, anti-inflammatory and antipyretic properties. These effects may be due to PONSTAN®'s dual action on prostaglandins, one of a number of hormone-like substances that participate in a wide range of body functions.

PONSTAN®, as a nonsteroidal anti inflammatory drug (NSAID), does NOT cure your illness or prevent it from getting worse. PONSTAN® can only relieve pain and reduce swelling as long as you continue to take it.

When it should not be used:

DO NOT TAKE PONSTAN® if you have any of the following medical conditions:

- **Heart bypass surgery (planning to have or recently had)**
- **Severe, uncontrolled heart failure**
- **Bleeding in the brain or other bleeding disorders**
- **Current pregnancy (after 28 weeks of pregnancy)**
- **Currently breastfeeding (or planning to breastfeed)**
- **Allergy to ASA (Acetylsalicylic Acid) or other NSAIDs (Nonsteroidal Anti-**
- **Inflammatory Drugs)**
- **Ulcer (active)**
- **Bleeding from the stomach or gut (active)**
- **Inflammatory bowel disease (Crohn's Disease or Ulcerative Colitis)**
- **Liver disease (active or severe)**
- **Kidney disease (severe or worsening)**
- **High potassium in the blood**

Patients who took a drug in the same class as PONSTAN® after a type of heart surgery (coronary artery bypass grafting (CABG)) were more likely to have heart attacks, strokes, blood clots in the leg(s) or lung(s), and infections or other complications than those who did NOT take that drug.

PONSTAN® should NOT be used in patients under 18 years of age since the safety and effectiveness have NOT been established.

What the medicinal ingredient is:

Mefenamic Acid 250 mg

What the non medicinal ingredient are:

Gelatin, Lactose, Sodium lauryl sulphate

What dosage forms it comes in:

Each capsule BP, contains 250 mg of Mefenamic acid

WARNING AND PRECAUTIONS

If you have, or previously had, any of the following medical conditions, see your health care provider to discuss treatment options other than PONSTAN®:

- **Heart Attack or Angina**
- **Stroke or Mini-stroke**
- **Loss of Vision**
- **Current Pregnancy (less than 28 weeks)**
- **Congestive Heart Failure**

Before taking this medication, tell your health care provider if you have any of the following:

- High blood pressure
- High cholesterol
- Diabetes mellitus or on a low sugar diet
- Atherosclerosis
- Poor circulation to your extremities
- Smoker or ex-smoker
- Kidney disease or urine problems
- Previous ulcer or bleeding from the stomach or gut
- Previous bleeding in the brain
- Bleeding problems
- Family history of allergy to NSAIDs, such as acetylsalicylic acid (ASA), celecoxib, diclofenac, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, mefenamic acid, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, rofecoxib, sulindac, tenoxicam, tiaprofenic acid, tolmetin, or valdecoxib (NOT a complete list)
- Family history of asthma, nasal polyps, long-term swelling of the sinus (chronic sinusitis) or hives
- Any other medical problem

Serious gastrointestinal toxicity such as bleeding, ulceration, and perforation, can occur at any time, with or without warning symptoms, if you are treated chronically with PONSTAN®.
If diarrhea or skin rash appear, you should discontinue PONSTAN® immediately.
Blood counts and liver function should be monitored during long-term therapy. PONSTAN® may enhance the effects of your oral anticoagulants medication.

Also, before taking this medication, tell your health care provider if you are planning to get pregnant.

While taking this medication:

- tell any other doctor, dentist, pharmacist or other health care professional that you see, that you are taking this medication, especially if you are planning to have heart surgery;
- do NOT drink alcoholic beverages while taking this medication because you would be more likely to develop stomach problems;
- fertility may be decreased. The use of PONSTAN® is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping PONSTAN® should be considered.

INTERACTIONS WITH THIS MEDICATION

Talk to your health care provider and pharmacist if you are taking any other medication (prescription or non-prescription) such as any of the following (NOT a complete list):

- Acetylsalicylic Acid (ASA) or other NSAIDs
  - e.g. ASA, celecoxib, diclofenac, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen
- Antacids
- Antidepressants
  - Selective Serotonin Reuptake Inhibitors (SSRIs) e.g. citalopram, fluoxetine, paroxetine, sertraline
- Blood pressure medications
- ACE (angiotensin converting enzyme) inhibitors
  - e.g. enalapril, lisinopril, perindopril, ramipril,
- ARBs (angiotensin II receptor blockers)
  - e.g. candesartan, irbesartan, losartan, valsartan

- Blood thinners
    - e.g. warfarin, ASA, clopidogrel
- Corticosteroids (including glucocorticoids)
    - e.g. prednisone
- Cyclosporin
- Digoxin
- Diuretics
    - e.g. furosemide, hydrochlorothiazide
- Lithium
- Methotrexate
- Oral contraceptives
- Oral hypoglycemics (diabetes medications)
- Tacrolimus

Your health care provider may prescribe low dose ASA (acetylsalicylic acid) as a blood thinner to reduce your risk of having a heart attack or stroke while you are taking PONSTAN®. Take only the amount of ASA prescribed by your health care provider. You are more likely to upset or damage your stomach if you take both PONSTAN® and ASA than if you took PONSTAN® alone.

PROPER USE OF THIS MEDICATION

Usual Dose

Medical Condition	Age Group	Starting Dose	Maximum Dose (per day)	Maximum Duration of Treatment (days)
Acute pain, headeach	>18 y.o	2 capsules of 250mg with meals	1250mg	7
Primary dysmenorrhea	>18 y.o	2 capsules of 250mg with meals	1250mg	3

Take PONSTAN® only as directed by your health care provider. **Do NOT take more of it, do NOT take it more often and do NOT take it for a longer period of time than your health care provider recommended. If possible, you should take the lowest dose of this medication for the shortest time period.** Taking too much PONSTAN® may increase your chances of unwanted and sometimes dangerous side effects, especially if you are elderly, have other diseases or take other medications.

If you will be using PONSTAN® for more than 7 days, see your health care provider regularly to discuss whether this medicine is working for you and if it is causing you any unwanted effects.

This medication has been prescribed specifically for you. Do NOT give it to anyone else. It may harm them, even if their symptoms seem to be similar to yours.

PONSTAN® is NOT recommended for use in patients under 18 years of age since safety and effectiveness have NOT been established.

PONSTAN® must be taken with food

Missed Dose

If a dose is missed, you should take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

Overdose

If you take more than the prescribed dose, contact your health care provider immediately.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

PONSTAN® may cause some side effects, especially when used for a long time or in large doses. When these side effects occur, you may require medical attention. Report all symptoms or side effects to your health care provider.

PONSTAN® may cause you to become drowsy or tired. Be careful about driving or participating in activities that require you to be alert. If you become drowsy,

dizzy or light-headed after taking PONSTAN®, do NOT drive or operate machinery.

Check with your health care provider IMMEDIATELY if you develop chills, fever, muscle aches or pains, or other flu like symptoms, especially if they occur before or together with a skin rash. These symptoms may be the first signs of a SERIOUS ALLERGIC REACTION to this medication.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM **All these side effects are rare.**		
Symptom	**STOP taking PONSTAN® and talk to your physician or pharmacist**	**STOP taking PONSTAN® and get emergency medical attention IMMEDIATELY**
Bloody or black tarry stools		✔
Shortness of breath, wheezing, any trouble breathing or chest tightness		✔
Skin rash, hives, swelling or itching		✔
Blurred vision, or any visual disturbance		✔
Any change in the amount or colour of your urine (red or brown)		✔
Any pain or difficulty experienced while urinating	✔	
Swelling of the feet, lower legs; weight gain	✔	
Vomiting or persistent indigestion, nausea, stomach pain or diarrhea	✔	
Yellow discolouration of the skin or eyes, with or without itchy skin	✔ Call your doctor immediately	
Malaise, fatigue, loss of appetite	✔	
Headaches, stiff neck	✔	
Mental confusion, depression	✔	
Dizziness, lightheadedness	✔	
Hearing problems	✔	

This is NOT a complete list of side effects. If you develop any other symptoms while taking PONSTAN®, see your health care provider. These side effects are rare.

HOW TO STORE IT

Do NOT keep outdated medicine or medicine no longer needed. Any outdated or unused medicine should be returned to your pharmacist.

Keep the capsules in a dry place at normal room temperature (15°C- 30°C) in the packaging that they come in.

Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

Online: www.healthcanada.gc.ca/medeffect

toll-free telephone: 1-866-234-2345

toll-free fax: 1-866-678-6789

Postage Paid Mail: Canada Vigilance Program
Health Canada
AL 0701C
Ottawa ON, K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph prepared for health professionals can be found at http://www.AspriPharma.com or by contacting the sponsor, Aspri Pharma Canada Inc. at 1-855-868-8440.

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