

# PONSTAN<sup>®</sup> Capsules

Mefenamic Acid

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about PONSTAN.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PONSTAN against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What PONSTAN is used for

PONSTAN is used to relieve the symptoms of period pain and treat heavy periods.

It also provides short term relief of pain in conditions such as:

- muscle and joint injuries such as sprains, strains and tendonitis
- dental pain.

PONSTAN containing mefenamic acid belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (or NSAIDs). These medicines work by relieving pain and inflammation.

Although PONSTAN can relieve the symptoms of pain and inflammation, it will not cure your condition.

Your doctor may have prescribed PONSTAN for another reason.

**Ask your doctor if you have any questions about why PONSTAN has been prescribed for you.**

PONSTAN is not addictive.

### Before you take PONSTAN

#### **When you must not take it**

**Do not take PONSTAN if:**

**1. you have an allergy to:**

- mefenamic acid or any of the ingredients listed at the end of this leaflet
- aspirin
- any other NSAID medicine including COX-2 inhibitors.

Many medicines used to treat headache, period pain or other aches and pains contain aspirin or NSAID medicines.

**If you are not sure if you are taking any of these medicines, ask your doctor or pharmacist.**

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting.

If you are allergic to aspirin or NSAID medicines and take PONSTAN, these symptoms may be severe.

**2. you had diarrhoea with this medicine in the past.**

Diarrhoea may recur if you take PONSTAN again.

**3. you have a gastric ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had gastric ulcers before.**

**4. you have or have had inflammation and/or ulceration of the lining of the stomach or bowel.**

Some examples of these conditions include Crohn's disease and ulcerative colitis.

**5. you have kidney disease.**

**6. you have severe heart failure.**

**7. you have liver failure.**

**8. you are about to have coronary artery bypass surgery.**

**9. children under 14 years of age.**

**Do not take PONSTAN if the packaging is torn or shows signs of tampering.**

**Do not take PONSTAN if the expiry date (EXP) printed on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work as well.

**If you are not sure if you should start taking PONSTAN contact your doctor or pharmacist.**

#### **Before you start to take it**

**Tell your doctor or pharmacist if you have any allergies to:**

- any other medicines including aspirin or other NSAID medicines

- any other substances, such as foods, preservatives or dyes.

**Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:**

- vomiting blood or bleeding from the back passage
- heart failure, heart attack, stroke
- heart disease. Use of PONSTAN may increase your risk of developing cardiovascular events (e.g. heart attack) even if you don't have a history of heart disease.
- high blood pressure
- blood clots
- a tendency to bleed or other blood problems such as anaemia
- heartburn, indigestion, stomach ulcer or other stomach problems
- bowel or intestinal problems such as ulcerative colitis
- diarrhoea
- asthma
- pinkish, itchy swellings on the skin (also called hives) or any other skin rash.

**Tell your doctor or pharmacist if you are using an intrauterine contraceptive device (IUCD).**

**Tell your doctor if you are pregnant or plan to become pregnant.**

PONSTAN may affect your developing baby if you take it during pregnancy. Pregnant woman taking PONSTAN should be closely monitored by their doctor.

**Tell your doctor if you are breastfeeding.**

PONSTAN passes into breast milk and may affect your baby.

Your doctor will discuss with you the benefits and risks of taking this medicine.

**If you have not told your doctor or pharmacist about any of the above, tell them before you take any PONSTAN.**

## ***Taking other medicines***

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

Some medicines may interfere with PONSTAN. These include:

- aspirin including low doses of aspirin used to prevent your blood from clotting in certain heart conditions
- warfarin or similar medicines including Eliquis, Xarelto or Pradaxa that are used to stop blood clots
- some medicines used to treat high blood pressure
- corticosteroids, medicines used to suppress the immune system or reduce inflammation
- some medicines used to treat diabetes
- lithium, a medicine used to treat mood swings in patients with bipolar disorder
- cyclosporin or tacrolimus, medicines used to suppress the immune system
- selective serotonin reuptake inhibitors, medicines used for depression
- methotrexate, a medicine used to treat arthritis and some cancers.

These medicines may be affected by PONSTAN, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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

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## **How to take PONSTAN**

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**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 on the pack, ask your doctor or pharmacist for help.**

### ***How much to take***

The usual dose of PONSTAN is 2 capsules (500 mg) three times daily with meals.

Your doctor may recommend a different dose. This may depend on your age, your condition and whether or not you are taking any other medicines.

**Take PONSTAN exactly as your doctor has prescribed.**

### ***How to take it***

**Swallow PONSTAN capsules whole with a full glass of water.**

Do not chew them.

**Take PONSTAN with or after food.**

This may help reduce the possibility of stomach upset.

### ***How long to take it***

**Do not take PONSTAN for longer than your doctor says.**

**Do not exceed the dosage recommended by your doctor.**

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

**If you need to take PONSTAN for a long time, see your doctor for regular check-ups so that he/she can monitor your condition and treatment.**

### ***If you forget to take it***

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go**

**back to taking your capsules as you would normally.**

**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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

### ***If you take too much (overdose)***

**Immediately telephone your doctor or Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much PONSTAN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

If you take too much PONSTAN, you may experience pain or tenderness in the stomach, diarrhoea, muscle twitches, seizure (fit), confusion, dizziness or hallucination.

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## **While you are taking PONSTAN**

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### ***Things you must do***

**If you become pregnant while taking PONSTAN tell your doctor immediately.**

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

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

**If you are going to have surgery, tell your doctor you are taking PONSTAN.**

**If you get an infection while using PONSTAN, tell your doctor.**

PONSTAN may hide some of the signs of an infection and may make

you think, mistakenly, that you are well or that it is not serious. Signs of an infection may include fever, pain, swelling and redness.

**If you need to have any medical tests while you are taking PONSTAN, tell your doctor.**

PONSTAN may affect the results of some tests.

### ***Things you must not do***

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

**Do not take PONSTAN 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 PONSTAN affects you.**

As with other NSAID medicines, PONSTAN may cause dizziness or light-headedness in some people. Make sure you know how you react to PONSTAN before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

Be careful of ingesting alcohol whilst taking PONSTAN. As with other NSAID medicines ingesting alcohol may increase your risk of developing gastro intestinal complications.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PONSTAN.**

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

It can be difficult to tell whether side effects are the result of taking

PONSTAN, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

If you are over 65 years of age you may have an increased chance of getting side effects.

**Do not be alarmed by the list of side effects.**

You may not experience any of them.

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

### ***Tell your doctor if...***

**Tell your doctor if you notice any of the following and they worry you:**

- stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps
- loss of appetite
- constipation, diarrhoea, pain in the stomach, wind
- fluid retention, swelling
- dizziness, light-headedness
- drowsiness
- nervousness
- headache
- sleeplessness.

These are the more common side effects of PONSTAN.

### ***Tell your doctor as soon as possible if...***

**Tell your doctor as soon as possible if you notice any of the following:**

- severe dizziness
- severe or persistent headache
- severe pain or tenderness in the stomach
- severe diarrhoea
- eye problems such as blurred vision or loss of colour vision
- ear pain
- fast or irregular heartbeats, also called palpitations
- excessive sweating

- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- worsening blood sugar levels in patients with diabetes
- signs of anaemia, such as tiredness, being short of breath, and looking pale
- a change in the colour of urine passed, blood in the urine
- a change in the amount or frequency of urine passed, burning feeling when passing urine
- bulky, grey or pale coloured stools
- yellowing of the skin and eyes, also called jaundice
- unusual weight gain, swelling of ankles or legs.

The above list includes serious side effects that may require medical attention.

### ***Go to hospital if...***

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:**

- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives
- fainting, seizures or fits
- pain or tightness in the chest
- fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light

- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Other side effects not listed above may also occur in some patients.

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

**Ask your doctor or pharmacist if you don't understand anything in this list.**

Some of the other possible side effects can only be found when your doctor does tests from time to time to check your progress.

## **After taking PONSTAN**

### ***Storage***

**Keep your capsules in the pack until it is time to take them.**

If you take the capsules out of the pack they will not keep well.

**Keep the capsules in a cool dry place where the temperature stays below 30°C.**

**Do not store PONSTAN or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep PONSTAN where children cannot reach it.**

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

### ***Disposal***

**If your doctor tells you to stop taking PONSTAN or the capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.**

## **Product description**

### ***What it looks like***

PONSTAN capsules have an ivory opaque body and an aqua blue opaque cap, and are marked in black with "Parke Davis" on the body and cap.

PONSTAN comes in blister packs of 50 capsules. This presentation is available only with a doctor's prescription.

### ***Ingredients***

#### **Active ingredient:**

Each PONSTAN capsule contains 250 mg mefenamic acid.

#### **Inactive ingredients:**

- lactose monohydrate
- titanium dioxide
- iron oxide yellow
- brilliant blue
- gelatin
- carbon black.

PONSTAN does not contain sucrose, gluten, tartrazine or any other azo dyes.

### ***Distributor***

PONSTAN is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

AUSTRALIA

Toll Free Number: 1800 675 229.

PONSTAN is supplied in New Zealand by:

Pfizer New Zealand Limited

PO Box 3998

Auckland NEW ZEALAND

Toll Free Number: 0800 736 363.

### ***Australian Registration Number***

AUST R 225658 - blister pack of 50

***Date of preparation***

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