

PONSTAN[®] 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 contains the active ingredient mefenamic acid.

PONSTAN belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (or NSAIDs).

PONSTAN relieves pain and reduces inflammation (swelling, redness and soreness) that may occur in the following:

- menstrual cramps (period pain)
- muscle and bone injuries such as sprains, strains, low back pain (lumbago), rheumatism and tendonitis
- after setting broken or dislocated bones
- dental pain

- headache

PONSTAN is also used to treat heavy menstrual periods.

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:

- PONSTAN or any of the ingredients listed at the end of this leaflet
- aspirin
- any other NSAID medicine

Many medicines used to treat headache, period pain and 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 are pregnant or intend to become pregnant.

PONSTAN may affect your developing baby if you take it during pregnancy.

3. you are breast-feeding or intend to breast-feed.

PONSTAN passes into breast milk and may affect your baby.

4. you had diarrhoea with this medicine in the past.

Diarrhoea may recur if you take PONSTAN again.

5. you have a peptic ulcer (ie stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before.

6. 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.

7. you have kidney disease.

8. you have severe heart failure.

9. you have liver failure.

10. you are about to have coronary artery bypass surgery.

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.

Do not give PONSTAN to a child under 14 years.

The safety and effectiveness of PONSTAN in children have not been established.

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 previously experienced ill effects from any medicine, whether it has been prescribed for you or you have bought it without prescription.

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 or 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
- asthma
- diarrhoea
- pinkish, itchy swellings on the skin (also called hives) or any other skin rash
- kidney or liver disease
- high blood pressure

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

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, salicylates or other NSAID medicines
- warfarin, a medicine 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 certain types of depression
- cyclosporine or tacrolimus, medicines used to suppress the immune system
- 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.

How to take PONSTAN

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 or bottle, ask your doctor or pharmacist for help.

How much to take

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

Take PONSTAN exactly as your doctor has prescribed.

Your doctor will tell you how many capsules you will need to take each day.

How to take it

Swallow PONSTAN capsules whole with a full glass of water. Do not chew them.

When to take it

Take the capsules with or straight after food with a full glass of water.

This may help reduce the possibility of stomach upset.

How long to take it

Do not use PONSTAN for longer than your doctor says.

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

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

For sprains and strains, PONSTAN is usually only needed for a few days.

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

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 the Australian Poisons Information Centre (telephone 13 11 26) or New Zealand National Poisons Information Centre (telephone 03 474 7000) 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 PONSAN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep these telephone numbers handy.

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

While you are using PONSAN

Things you must do

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

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

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

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

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

PONSAN 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 PONSAN, tell your doctor.

PONSAN may affect the results of some tests.

Tell your doctor if you feel PONSAN is not helping your condition.

Your doctor may need to change your medicine.

Tell your doctor if, for any reason, you have not taken PONSAN exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

Things you must not do

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

Do not use PONSAN 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 PONSAN affects you.

As with other NSAID medicines, PONSAN may cause dizziness or light-headedness in some people. Make sure you know how you react to PONSAN 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.

Side effects

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

PONSAN helps most people with painful or heavy menstrual periods, pain or inflammation, but it may have unwanted side effects in a few people. If you are over 65 years of age, you may have an increased chance of getting side effects.

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.

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

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
- dizziness, light-headedness
- drowsiness
- nervousness
- headache
- sleeplessness

These are the more common side effects of PONSAN. These are usually mild.

Tell your doctor immediately if you notice any of the following:

- severe dizziness
- severe or persistent headache
- severe pain or tenderness in the stomach

- eye problems such as blurred vision or loss of colour vision
- fast or irregular heartbeats, also called palpitations
- 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
- 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
- yellowing of the skin and eyes, also called jaundice
- severe diarrhoea
- worsening blood sugar levels in patients with diabetes
- ear pain
- excessive sweating
- bulky, grey or pale coloured stools
- unusual weight gain, swelling of ankles or legs

Stop taking PONSTAN and 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 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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using PONSTAN

Storage

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

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

Keep the capsules in a cool dry place where the temperature stays below 30 degrees 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 20 capsules and is available without a doctor's prescription. PONSTAN also comes in bottles of 50 capsules and is available only with a doctor's prescription.

Ingredients

Active ingredient:

Each PONSTAN capsule contains 250mg mefenamic acid.

Inactive ingredients:

- lactose
- 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 Ltd
PO Box 3998
Auckland NEW ZEALAND
Toll Free Number: 0800 736 363

®Registered Trademark

Australian Registration Number

- AUST R 14388 - blister pack of 20
- AUST R 14387 - bottle of 50

This leaflet was prepared in
December 2011.