

PONSTAN[®] Capsules

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using PONSTAN?

PONSTAN contains the active ingredient mefenamic acid. 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.

For more information, see Section [1. Why am I using PONSTAN?](#) in the full CMI.

2. What should I know before I use PONSTAN?

Do not use if you have ever had an allergic reaction to mefenamic acid, aspirin, any other NSAID, or any of the ingredients listed at the end of the CMI. Do NOT also use if you have any of the conditions listed in Section [2. What should I know before I use PONSTAN?](#) in the full CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use PONSTAN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PONSTAN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use PONSTAN?

- Swallow PONSTAN capsules whole with a full glass of water.
- Do not chew the capsules.
- Take PONSTAN with or after food. This may help reduce the possibility of stomach upset.

More instructions can be found in Section [4. How do I use PONSTAN?](#) in the full CMI.

5. What should I know while using PONSTAN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using PONSTAN.• Call your doctor immediately if you become pregnant while taking PONSTAN.
Things you should not do	<ul style="list-style-type: none">• 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.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how PONSTAN affects you. PONSTAN may cause dizziness or light-headedness in some people. If this occurs do not drive.
Drinking alcohol	<ul style="list-style-type: none">• If you drink alcohol, it may increase your risk of developing gastrointestinal complications.
Looking after your medicine	<ul style="list-style-type: none">• Store it in a cool dry place away from moisture, heat or sunlight, below 30°C.

For more information, see Section [5. What should I know while using PONSTAN?](#) in the full CMI.

6. Are there any side effects?

Common side effects may include stomach upset, diarrhoea or constipation, vomiting or light headedness. More serious side effects may include severe allergic reaction, black stools or vomit that looks like coffee grounds, bleeding or bruising more easily than usual, swollen ankles, bleeding from the back passage or a stiff neck.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

PONSTAN[®] Capsules

Active ingredient(s): Mefenamic Acid

Consumer Medicine Information (CMI)

This leaflet provides important information about using PONSTAN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PONSTAN.**

Where to find information in this leaflet:

- [1. Why am I using PONSTAN?](#)
- [2. What should I know before I use PONSTAN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PONSTAN?](#)
- [5. What should I know while using PONSTAN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using PONSTAN?

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

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

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.

2. What should I know before I use PONSTAN?

Warnings

Do not use PONSTAN in children under 14 years of age.

Do not use PONSTAN if:

1. You are allergic to:
 - Mefenamic acid, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
 - 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.

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 and require urgent medical attention.

2. You are pregnant and in the third trimester of your pregnancy.
3. You are breastfeeding.
4. You had diarrhoea with this medicine in the past.
Diarrhoea may recur if you take PONSTAN again.
5. You have a gastric ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had gastric 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 or have had recent coronary artery bypass surgery.
11. If the packaging is torn or shows signs of tampering.
12. 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.

Check with your doctor if you:

- Are allergic to any other medicine including aspirin or other NSAID medicine.
- Are allergic to any other substances such as foods, preservatives or dyes.
- Take any medicines for any other condition
- Are using an intrauterine contraceptive device (IUCD).
- Have or have a history of any other medical conditions including:
 - 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

PONSTAN is not to be used at all during the third trimester of pregnancy.

PONSTAN should not be used during the first two trimesters of pregnancy unless the expected benefits to the mother outweigh the risks to the baby. Seek advice from your doctor.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

PONSTAN is not to be used while breastfeeding.

PONSTAN passes into breast milk and may affect your baby.

3. What if I am taking other medicines?

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

Some medicines may interfere with PONSTAN and affect how it works.

- Aspirin including low doses of aspirin used to prevent your blood from clotting in certain heart conditions
- Warfarin or similar medicines including apixaban, rivaroxaban or dabigatran 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
- Ciclosporin 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PONSTAN.

4. How do I use PONSTAN?

How much to take / use

- 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.
- Follow the instructions provided and use PONSTAN until your doctor tells you to stop.

How to use PONSTAN

Swallow PONSTAN capsules whole with a full glass of water.

Do not chew the capsules.

Take PONSTAN with or after food. This may help reduce the possibility of stomach upset.

When to take / use PONSTAN

- PONSTAN should be taken at the first sign of pain to maximise effectiveness.
- 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 use PONSTAN

If you miss your dose at the usual time and 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 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 use too much PONSTAN

If you think that you have used too much PONSTAN, you may need urgent medical attention.

You should immediately:

- Phone the Poisons Information Centre (**by calling 13 11 26**), or
- Contact your doctor, or

- Go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using PONSTAN?

Things you should do

- If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking PONSTAN
- Tell all 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 need to have any medical tests while you are taking PONSTAN, tell your doctor.

PONSTAN may affect the results of some tests.

Call your doctor straight away if you:

- become pregnant while taking PONSTAN.
- get an infection while using PONSTAN.

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.

Remind any doctor or dentist you visit that you are using PONSTAN.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PONSTAN affects you.

PONSTAN may cause dizziness or light-headedness, drowsiness and blurred vision 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, drowsy or have changes to vision. If this occurs do not drive.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful drinking alcohol whilst taking PONSTAN. As with other NSAID medicines, alcohol may increase your risk of developing gastrointestinal complications.

Looking after your medicine

Store it in a cool dry place away from moisture, heat or sunlight, below 30°C; for example, do not store it:

- In the bathroom or near a sink, or
- In the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
<p>Gastrointestinal related symptoms:</p> <ul style="list-style-type: none"> • Stomach upset including nausea (feeling sick) • Vomiting • Heartburn • Indigestion • Cramps • Loss of appetite • Constipation • Diarrhoea • Pain in the stomach • Wind <p>Alertness related symptoms</p> <ul style="list-style-type: none"> • Dizziness, light-headedness • Drowsiness • Sleeplessness <p>Other</p> <ul style="list-style-type: none"> • Fluid retention, swelling • Nervousness • Headache 	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Severe allergic reaction symptoms</p> <ul style="list-style-type: none"> • Swelling of the face, lips or tongue which may cause 	<p>Stop use, call your doctor straight away, or go straight</p>

Serious side effects	What to do
<p>difficulty in swallowing or breathing</p> <ul style="list-style-type: none"> Asthma, wheezing, shortness of breath Sudden or severe itching, skin rash, hives Pain or tightness in the chest <p>Gastrointestinal symptoms:</p> <ul style="list-style-type: none"> Vomiting blood or material that looks like coffee grounds Severe pain or tenderness in the stomach Severe diarrhoea <p>Skin and blood related symptoms:</p> <ul style="list-style-type: none"> Bleeding or bruising more easily than normal Reddish or purplish blotches under the skin Severe blistering and/or peeling of layers of skin Yellowing of the skin and eyes, also called jaundice Signs of low iron levels (anaemia), such as tiredness, being short of breath, and looking pale <p>Alertness problems</p> <ul style="list-style-type: none"> Fainting, seizures or fits Severe dizziness <p>Changes to urine and stools:</p> <ul style="list-style-type: none"> Bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea 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 <p>Eye and ear symptoms:</p> <ul style="list-style-type: none"> Extreme sensitivity to bright light Eye problems such as blurred vision or loss of colour vision Ear pain <p>Head and neck:</p> <ul style="list-style-type: none"> Stiff neck Severe or persistent headache <p>Other symptoms:</p>	<p>to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. 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 Worsening blood sugar levels in patients with diabetes Unusual weight gain, swelling of ankles or legs. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What PONSTAN contains

Active ingredient (main ingredient)	Mefenamic acid
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> Lactose monohydrate Titanium dioxide Iron oxide yellow Brilliant blue Gelatin Carbon black <p>PONSTAN does not contain sucrose, gluten, tartrazine or any other azo dyes.</p>

Do not take this medicine if you are allergic to any of these ingredients.

What PONSTAN 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. (AUST R 225658).

Who distributes PONSTAN

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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