

Package leaflet: Information for the user

Ponstan 250 mg Capsules

Mefenamic acid

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ponstan is and what it is used for
2. What you need to know before you take Ponstan
3. How to take Ponstan
4. Possible side effects
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1. What Ponstan is and what it is used for

Ponstan capsules contain mefenamic acid which is a non-steroidal anti-inflammatory drug (NSAID).

They can help to relieve:

- symptoms of inflammation, such as redness and swelling
- pain and discomfort caused by arthritis, muscular or rheumatic disorders
- headache or toothache
- fever in children over 12 years
- pain after operations, trauma
- childbirth pain
- painful or heavy periods
- symptoms of premenstrual syndrome (PMS).

2 What you need to know before you take Ponstan

Do not take Ponstan

- if you are allergic to mefenamic acid, to any other anti-inflammatory medicines (such as aspirin, ibuprofen, celecoxib), or any of the other ingredients of this medicine (listed in section 6)
- if you have, or have ever had, stomach or intestinal conditions such as peptic ulcer, bleeding in the stomach, intestines or bowel, or severe gastritis, especially if you have taken NSAIDs before
- if you have an inflammatory bowel disease (e.g. ulcerative colitis, Crohn's disease)
- if you have severe heart, liver or kidney problems

- if you are seeking pain relief after heart bypass surgery
- if you take any other non-steroidal anti-inflammatory drug (NSAID) including cyclooxygenase-2-inhibitor (e.g. ibuprofen, diclofenac, celecoxib, etoricoxib)
- if you are pregnant or breast-feeding.

If any of the above apply to you, speak to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ponstan:

- if you are taking any other anti-inflammatory medicines including steroids (e.g. prednisolone)
- if you are taking aspirin or medicines that thin the blood (e.g. warfarin, clopidogrel)
- if you are taking antidepressants called selective serotonin re-uptake inhibitors (SSRIs) (e.g. paroxetine)
- if you have kidney or liver problems. Your doctor may check your kidney or liver function before and during treatment
- if you are elderly (see section 3)
- if you are trying to become pregnant (see section on Fertility)
- if you have stomach or digestive tract problems or if you have ever had an upset stomach after taking pain killers such as aspirin. Bleeding in the stomach or gut can occur in patients taking Ponstan
- if you have a bleeding disorder or if you are going to have a major operation. Ponstan can affect the clotting of your blood. It can make you bleed more and for longer than usual
- if you have asthma, or a history of asthma, as this medicine may cause breathing difficulties
- if you have a connective tissue disorder, e.g. Systemic Lupus Erythematosus (SLE)
- if you have epilepsy
- if you are dehydrated (thirsty with dry skin, dark urine, dry mouth, headache)
- if you have heart problems, previous stroke or think that you might be at risk of these conditions (e.g. if you have high blood pressure, fluid retention, diabetes or high cholesterol or are a smoker). Additional monitoring may be carried out by your doctor.

Medicines such as Ponstan may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses and prolonged treatment. **Do not exceed** the recommended dose or duration of treatment.

Blood tests

Your doctor may test your blood during treatment.

Children

Do not give this medicine to children under 12 years of age

Other medicines and Ponstan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may be affected by Ponstan or they may affect how well Ponstan will work. Tell your doctor or pharmacist if you are taking:

- medicines that can increase the chance of getting ulcers or a bleed in the stomach or gut, such as:
 - o corticosteroids used to treat arthritis and inflammation
 - o medicines used to thin the blood (e.g. warfarin, aspirin, clopidogrel)

- antidepressants called selective serotonin re-uptake inhibitors (SSRIs) (e.g. paroxetine)
 - any other anti-inflammatory medicines (e.g. diclofenac, celecoxib)
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- prophylactic treatment of cardiovascular disease with aspirin can be interfered
 - medicines used for high blood pressure (e.g. atenolol, ramipril, valsartan)
 - diuretics (water tablets) or heart medicines (e.g. digoxin, sotalol, diltiazem)
 - some diabetic medicines (e.g. glipizide, glibenclamide)
 - medicines which suppress the immune system (e.g. ciclosporin, tacrolimus, methotrexate)
 - lithium, a medicine used to treat mood swings and some types of depression
 - a medicine usually prescribed through hospitals, called mifepristone (taken within the last 12 days)
 - quinolone antibiotics (antibiotics used to treat infections)
 - aminoglycoside antibiotics, used under medical supervision in hospitals
 - zidovudine, a medicine used for HIV
 - probenecid, a medicine used in special cases, to protect the kidneys
 - medicines which bind to protein in the blood - (check with your pharmacist).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Mefenamic acid will be passed to your unborn baby.

DO NOT take these capsules if you are pregnant or planning to become pregnant unless advised to by your doctor, as it can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

If taken for more than a few days from 20 weeks of pregnancy onward, Ponstan can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby.

Breast-feeding

Mefenamic acid passes into breast milk and can affect the baby. You should not take the capsules while breast-feeding unless advised by your doctor.

Fertility

DO NOT take the capsules if you are trying to become pregnant, as they may make it more difficult to get pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

Ponstan may cause drowsiness, dizziness, tiredness or affect your vision. If any of these occur do not drive, use machinery, or perform any tasks that may require you to be alert.

Ponstan contains lactose and sodium laurilsulfate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3 How to take Ponstan

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Take the capsules with or immediately after a **meal**.
- Do NOT drink **alcohol** while taking Ponstan.
Alcohol and smoking can irritate the stomach and make some of the side effects worse.

Dose

Adults

The recommended dose is 2 capsules three times a day.

Elderly patients (over 65 years)

Elderly patients are at a higher risk of side effects and should take the lowest effective dose for the shortest possible time, with additional monitoring carried out by their doctor.

Use in children

Ponstan is NOT suitable for children under 12 years.

If you take more Ponstan than you should

If you take more capsules than you should you may harm your stomach, kidneys and you may get seizures (fits).

1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the container and any remaining capsules with you so that people can see what you have taken.
3. Do this even if you feel well.

If you forget to take Ponstan

If you forget to take a dose take it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Do not be alarmed by this list of possible side effects. You may not experience any of them.

STOP taking the capsules and **seek medical help immediately** if you have any of the following **allergic reactions**:

- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
 - severe itching of the skin, with a red rash or raised lumps
 - blistering of the mouth, eyes, and genital region, and patchy areas of rash, peeling skin
- or any of the following reactions**
- diarrhoea
 - passing blood in your stools (faeces/motions)
 - passing black tarry stools
 - vomiting any blood or dark particles that look like coffee grounds.

Seek immediate medical attention if you have any of the following symptoms:

- indigestion or heartburn, abdominal pain (pain in your stomach) or other abnormal stomach symptoms, nausea (feeling sick), vomiting
- any unusual bruising or bleeding, for example nose-bleeds, pinpoint red spots on the skin, unusual purple bruise-like rash on the skin or in the mouth
- signs of anaemia such as feeling tired, breathless and looking pale
- fever, sore throat, mouth ulcers, repeated infections or infections that will not go away. This may be due to a low level of white blood cells
- signs of low sodium levels such as headache, nausea, vomiting, tiredness, muscle cramps
- sudden headache, stiff neck, fever, sensitivity to bright light, drowsiness and muscle pain, with or without a rash
- seizures (fits)
- fever, rash, nausea, aches and pains, passing more or less urine than usual, passing red urine or passing urine at night. This may be due to changes in your kidneys
- sudden or progressive loss or blurring of vision, loss of colour vision, eye pain which worsens with eye movement
- headache, in particular on waking in the morning. This may be due to high blood pressure
- pain behind the ribs radiating towards the back, often worse when lying down, nausea, vomiting, fever. This may be due to inflammation of your pancreas
- yellowing of your skin or eyes, pale faeces and dark urine, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness. This may be due to changes in your liver.

Tell your doctor if you get any of the following side effects:

- head-spins (vertigo)
- fatty stools
- sweating
- rapid heartbeat (palpitations)
- mental confusion
- loss of appetite
- constipation or bloating
- blurred vision, eye irritation
- feeling ill (malaise)

- ringing or buzzing in the ears (tinnitus)
- numbness or tingling in hands or feet
- sudden poor blood sugar control if you have diabetes. Your doctor or pharmacist can measure your sugar levels
- asthma or asthma that is worse than usual
- swelling of your hands and feet (around the ankles)
- sore mouth (pain or ulcers on the tongue, cheeks, lips, throat or gums)
- dizziness, drowsiness, feeling lethargic and tired
- signs of low blood pressure such as light-headedness
- reactions to the sun. Your skin may become red, painful and swollen - do not sunbathe, use a sun bed, or expose your skin to artificial UV light.
- depression
- inability to sleep
- hallucinations
- nervousness
- ear pain

Medicines such as Ponstan may be associated with a small increased risk of heart attack or stroke. (See section 2 - end of 'Warnings and precautions').

Urine tests

Tell the doctor if you are having urine tests, as your medicine may affect the results.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ponstan

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister, carton/container after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ponstan contains

- The active substance is mefenamic acid. Each capsule contains 250 mg mefenamic acid.
- The other ingredients are:

lactose monohydrate, sodium laurilsulfate, gelatin, purified water.

The capsule shell contains:

gelatin, erythrosine (E127), quinoline yellow (E104), titanium dioxide (E171), patent blue V (E131).

The printing ink contains either shellac, black iron oxide (E172), propylene glycol (E1520), ammonium hydroxide (E527) **or** shellac, propylene glycol (E1520), strong ammonia solution, potassium hydroxide (E525), black iron oxide (E172).

(See end of section 2 for further information on lactose and sodium).

What Ponstan looks like and contents of the pack

Ponstan Capsules are ivory and aqua blue hard gelatin capsules marked 'Ponstan 250'.

They are available in blister packs containing 6, 10, 12, 30, 42 or 100 capsules and in containers of 100 or 500 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Chemidex Pharma Ltd
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