

Package leaflet: Information for the user

Ponstan Forte 500 mg Film-coated Tablets

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

Ponstan Forte tablets 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
- 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 Forte

Do not take Ponstan Forte:

- 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 Forte:

- 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 ever had an upset stomach after taking pain killers such as aspirin. Bleeding in the stomach or gut can occur in patients taking Ponstan Forte
- if you have a bleeding disorder or if you are going to have a major operation. Ponstan Forte 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 Forte 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.

Other medicines and Ponstan Forte

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 Forte or they may affect how well Ponstan Forte 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:
 - corticosteroids used to treat arthritis and inflammation
 - 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)
- 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).

Blood tests

Your doctor may test your blood during treatment.

Pregnancy, breast-feeding and fertility

Pregnancy:

Mefenamic acid may be passed to your unborn baby. DO NOT take these tablets if you are pregnant or planning to become pregnant unless advised by your doctor.

Breast-feeding:

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

Fertility:

DO NOT take the tablets 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.

Ask your doctor for advice before taking any medicine.

Driving and using machines

Ponstan Forte 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 Forte contains lactose, sunset yellow and sodium

- **lactose**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- **sunset yellow (E110)**
This may cause allergic reactions.
- **sodium**
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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3. How to take Ponstan Forte

Always take this medicine exactly as your doctor has told you and always read the label. Your doctor will decide on the appropriate dose to suit your condition. Check with your doctor or pharmacist if you are not sure.

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

Doses

Adults and the elderly: the usual dose is 1 tablet three times a day.

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: This medicine is NOT suitable for children under 12 years.

If you take more Ponstan Forte than you should

If you take more tablets 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 tablets 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 Forte

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 tablets 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, vomiting 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 Forte 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
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ponstan Forte

- 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/bottle/container after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°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 Forte contains

- The active substance is mefenamic acid. Each tablet contains 500 mg of mefenamic acid.
- The other ingredients are: lactose monohydrate, pregelatinised maize starch, maize starch, povidone, silicon dioxide, talc, magnesium stearate, croscarmellose sodium (type A), sodium laurilsulfate.
The film coating contains: hypromellose, titanium dioxide (E171), lactose monohydrate, macrogol 4000, vanillin, quinoline yellow (E104), sunset yellow (E110).
The polish contains: purified water, beeswax, carnauba wax yellow, polysorbate 20, sorbic acid (E200).
(See end of Section 2 for further information on sodium, lactose and sunset yellow).

What Ponstan Forte looks like and contents of the pack

Ponstan Forte Tablets are yellow, film-coated tablets, marked 'PONSTAN FORTE' on one side. They are available in blister packs of 100 tablets, plastic containers of 100 or 500 tablets, and in plastic bottles of 6, 12, 100 and 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Chemidex Pharma Ltd, Chemidex House, Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB, UK.
Manufacturer: Dales Pharmaceuticals Ltd, Snaygill Industrial Estate, Keighley Road, Skipton, BD23 2RW, UK

This leaflet was last revised in June 2018.

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