Package leaflet: Information for the user

PONSTAN®
(Mefenamic Acid)

Read all of this leaflet carefully before you receive 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. 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

Ponstan contains the active ingredient mefenamic acid, a substance which in addition to a pain-relieving effect has marked anti-inflammatory and fever-reducing effects. Ponstan is used to treat:
- sudden onset or persistent pain in rheumatic diseases , muscle pain, pain in the spinal cord area (e.g. vertebral discs, shoulder or neck pain),
- pain following surgery, injuries or dental procedures,
- head, tooth and ear ache,
- painful and/or excessive menstrual bleeding.

Ponstan is also indicated for fever reduction and pain relief in common colds as well as other febrile illnesses, in particular of those in the respiratory system.

Subject to prescription by a doctor.

2. What you need to know before you receive Ponstan

Ponstan should not be taken

- if you are allergic to any of the ingredients or if you have experienced shortness of breath or allergy-type skin reactions after taking acetylsalicylic acid or other analgesic or anti-inflammatory drugs, so-called non-steroidal anti-inflammatory drugs (NSAIDs),
- in the last trimester of pregnancy,
- while breast-feeding,
- if you have active peptic and/or duodenal ulcers or gastrointestinal bleeding,
- if you have chronic bowel inflammation (Crohn's disease, ulcerative colitis),
- if you have severe liver or kidney dysfunction,

- if you have a severe cardiac output deficiency,
- to treat pain after a coronary bypass surgery on the heart (in particular, when using a heart-lung machine).

Warnings and Precautions

During treatment with Ponstan mucosal ulcers as well as mucosal bleeding (in rare cases) and gastrointestinal perforation (in isolated cases) may occur in the upper gastrointestinal tract. These complications may develop at any time during treatment, even without warning signs. In order to reduce this risk, your doctor will prescribe the lowest effective dose for the shortest duration of treatment possible.

The concomitant ingestion of alcoholic beverages may also increase the risk of side effects in the upper gastrointestinal tract.
Contact your doctor if you experience persistent diarrhoea , stomach pain and/or if you suspect a connection with the use of

this medicine.

For certain pain-relieving medicines, so-called COX-2 inhibitors, an increased risk for heart attack and stroke was observed at high doses and/or during long-term treatment. Whether this risk also applies to Ponstan is not yet known. If you have suffered from a heart attack, stroke or venous thrombosis in the past, or if you have risk factors (such as high blood pressure, diabetes, high blood lipid values, smoking), your doctor will decide whether you can use Ponstan nevertheless. Inform your doctor about this in any case.

Using Ponstan can affect the function of your kidneys, which can result in blood pressure increase and/or fluid retention (oedema). Tell your doctor if you suffer from heart or kidney disease, if you are taking medicines to treat high blood pressure (e.g. diuretics, ACE inhibitors), or in case of an increased fluid loss, for example due to profuse sweating.

Severe skin reactions have been reported in connection with the treatment with nonsteroidal antirheumatics. The greatest risk of such reactions seems to exist at the start of treatment. If a skin rash occurs, including fever, lesions of the mucosa, blisters or other signs of an allergy, you should suspend treatment with Ponstan and go for immediate medical treatment as these may be the first signs of a very serious skin reaction (see 4. Possible side effects)

Other NSAIDs, as used to treat pain and arthritis or - such as acetyl salicylic acid - as anti-platelet drug, should not be used concomitantly with Ponstan as they increase the risk of side effects. This also applies to concomitant use of cortisone-containing anti-inflammatory agents, anti-coagulant medicines (anti-clotting medicines) or serotonin reuptake inhibitors, used to treat depression, for example. Please tell your doctor if you are using any of these medicines at the same time as Ponstan. Also tell your doctor if you suffer from asthma, gastrointestinal, liver, cardiovascular (heart disease)or kidney disease, epilepsy, blood-clotting disorders or elevated blood glucose levels or have had these conditions in the past and are taking appropriate medicines.

Stop taking Ponstan and tell your doctor **immediately** if you experience one or several of the following symptoms: allergic reaction with swelling of the face, mouth, tongue or throat, often combined with rash, redness, fewer and/or collapse.

possible side effects such as drowsiness, fatigue, dizziness or visual disturbances, this medicine may affect your ability to react, to drive or to use tools or machines.

Tell your doctor or pharmacist also if you
- suffer from other illnesses,
- have any allergies or
- are using other medicines (including those bought over the counter).

Pregnancy and breast-feeding

You should not take Ponstan unless absolutely necessary and prescribed by a doctor. If taken during the first 6 months of pregnancy, the dose should be kept as low and the duration of treatment as short as possible.
Taking nonsteroidal antirheumatics (NSAIDs) from the 20th week of pregnancy onwards may harm your unborn child. If you have to take NSAIDs for more than 2 days, your doctor may need to monitor the volume of amniotic fluid in the womb and the heart of the unborn child.

Ponstan must not be used in the third trimester of pregnancy.

Ponstan should not be used while breast-feeding.

Tell your doctor if you are pregnant or breast-feeding in any case.

3. How Ponstan is given

Always keep to the dosage prescribed by your doctor. The usual dose is:
- For adults and children over 14 years of age: 1 Ponstan film-coated tablet 3 times daily together with food. If necessary, this dose can be reduced or increased. However, daily dosage should not exceed 2.0 g (= 4 tablets of 500 mg and 8 tablets of 250 mg)

For children 14 years of age, your doctor will adjust the dose according to age.

Do not deviate from the prescribed dosage. If you believe that the effect of the medicine is too weak or too strong, talk to your doctor or pharmacist.

4. Possible side effects

The following side effects may occur while taking Ponstan:

Common (affecting between 1 and 10 patients in every 100)

Diarrhoea, stomach pain, nausea or vomiting.

Uncommon (affecting between 1 and 10 patients in every 1000)

Loss of appetite, heartburn, wind, constipation, other gastrointestinal disorders, hypersensitivity reactions of the skin (rash, itching), hives and sweating.

Rare (affecting between 1 and 10 patients in every 10'000)

Swelling of the skin, face and tongue, headache, dizziness, fatigue, drowsiness, insomnia, nervousness, depression, convulsions, palpitations, swelling of the ankles, feet and legs (symptoms of heart weakness), high or low blood pressure, breathing problems, changes in glucose metabolism in diabetic patients, inflammation of the pancreas, ear pain, ringing in the ears (tinnitus), eye irritation, transient loss of colour vision or other visual disturbances.

Very rare (affecting fewer than 1 out of 10'000 patients)

Severe allergic reactions and skin allergies with blistering. If you notice any initial symptoms of allergic side effects such as breathing problems or skin rash, stop taking Ponstan and contact your doctor.

Liver (e.g. jaundice) and kidney dysfunction, changes in blood count as well as hypothermia in pediatric patients. Therefore, if Ponstan has to be used long term, it is important to comply with the regular check-up examinations prescribed by your doctor

Frequency not known

A severe skin reaction known as DRESS syndrome may occur. The symptoms of DRESS include skin rash, fever, swollen lymph nodes and high eosinophil counts (a form of white blood cells).

If you experience throat pain, high fever and possibly, swelling of the lymph nodes in the neck region (a very rarely observed condition) or pain in the upper abdomen and/or black discolouration of the stool, stop taking this medicine and contact your doctor immediately.

If you experience any side effects, talk to your doctor, pharmacist. This particularly includes any possible side effects not listed in this leaflet.

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 the national reporting system and include batch/Lot number if available. By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Ponstan

Ponstan® Tablets 250mg:

Pack (Nature & Content of Container)	**Shelf-life**	**Storage Conditions**
Blisters pack, 600 tablets per blister	60 months	Avoid exposure to heat and sunlight. Keep in a dry place.

Ponstan® Forte Tablets 500mg:

Pack (Nature & Content of Container)	Shelf-life	Storage Conditions
Blisters pack, 200 tablets per blister	60 months	Avoid exposure to heat and sunlight. Keep in a dry place.

Store at room temperature or below 30°C.
Keep out of the reach of children.

6. Contents of the pack and other information

What Ponstan contains

Ponstan® Tablets 250mg:
Croscarmellose sodium, Lactose EP-NF sprayed dried, Microcrystalline Cellulose M-102, Stearic Acid Powder.

Ponstan® Forte Tablets 500mg:
Sodium Lauryl Sulphate, Polyvinylpyrollidone (Povidone USP), Isopropyl Alcohol, Vanillin, Corn Starch, FD & C Yellow No. 5 Al. Lake, Silicon Dioxide Colloidal, Micrcrystalline Cellulose, Magnesium Stearate.

What Ponstan looks like and contents of the pack

Ponstan® and Ponstan® Forte Tablets contain less than 1 mmol sodium (23 mg) per each tabletBlister packs containing Tablets.

Ponstan® Tablets 250mg:
Each pack contains 600 tablets in 60 blisters.

Ponstan® Forte Tablets 500mg
Each pack contains 200 tablets in 20 blisters.

Ponstan/PIL/PK-01
According to Ponstan/LPD/PK-01 Switzerland Approved SmPC dated: 23 December 2022 & approved information in Pakistan