PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PONSTAN® 250 mg CAPSULES

Mefenamic acid

Contains sugar

Each PONSTAN 250 mg capsule contains 77,610 mg lactose

Read all of this leaflet carefully before you start taking PONSTAN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PONSTAN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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
5. How to store PONSTAN
6. Contents of the pack and other information

1. What PONSTAN is and what it is used for

PONSTAN is effective in providing pain relief, reducing swelling and inflammation and lowering fever.

Your doctor will prescribe PONSTAN to treat sudden onset of pain or persistent pain and inflammation of the joints, muscle pain, headache, toothache and painful and/or heavy menstrual periods.

2. What you need to know before you take PONSTAN

Do not take PONSTAN

- if you are hypersensitive (allergic) to mefenamic acid , other nonsteroidal anti-inflammatory drugs (NSAIDs) or any of the other ingredients of PONSTAN (listed in section 6)
- if you have had an allergic reaction such as an itchy skin rash, runny nose, or wheezing after taking aspirin or other nonsteroidal anti-inflammatory medicines
- if you have or have had inflammation, ulcers, bleeding or rupture in the walls of your gastrointestinal tract
- if you have a history of stomach or intestinal problems after taking aspirin or other nonsteroidal anti-inflammatory medicines
- if you have heart failure
- if you are having surgery on the blood vessels in your heart (coronary artery bypass surgery)
- if you have liver or kidney disease
- if you have epilepsy
- if you are at 20 weeks or later of pregnancy
- if you are breastfeeding

Warnings and precautions

Take special care with PONSTAN

- if you are taking other nonsteroidal anti-inflammatory medicines
- if you have a history of heart disease or problems with circulation in your blood vessels
- if you have high blood pressure
- if you are taking medicines to treat or prevent blood clots
- if you have a history of stomach or intestinal disease
- if you develop diarrhoea when taking PONSTAN; stop taking PONSTAN immediately if diarrhoea occurs
- if you develop any severe skin reactions or hypersensitivity while taking PONSTAN; stop taking PONSTAN immediately if skin reactions including rash, redness, blisters or itching occur

- if you develop symptoms of a serious hypersensitivity reaction called DRESS, including skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of the internal organs; stop taking PONSTAN immediately if these symptoms occur
- if you develop a serious skin reaction called generalized bullous fixed drug eruption (GBFDE), caused by allergic reaction to the medicine, which includes widespread, painful and blistering skin lesions that tend to appear in the same locations or over the whole body
- if you have asthma and are sensitive to aspirin
- if you develop a lower than normal amount of red blood cells (anaemia)
- if you are dehydrated from loss of fluid or taking water tablets
- if you are elderly because your risk of side effects may be increased

Some people will need special care from their doctor or health care provider when they are taking PONSTAN and will need testing of blood counts and liver function.

If you take nonsteroidal anti-inflammatory medicines including PONSTAN at 20 weeks or later of pregnancy it can harm your unborn baby.

Other medicines and PONSTAN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines that may interact with PONSTAN include:

- medicines used to treat or prevent blood clots (e.g. warfarin) ; combined use with PONSTAN may cause a harmful increase in the effects of these medicines
- medicines used to treat high blood pressure; combined use with PONSTAN may decrease the effects of these medicines
- lithium, a medicine used to treat mood swings and some types of depression; combined use with PONSTAN may cause a harmful increase in the levels of this medicine
- aspirin and other nonsteroidal anti-inflammatory medicines or corticosteroids (cortisone-like medicines); combined use with PONSTAN may cause an increase in side effects, including risk of ulcers, bleeding

or rupture in the walls of the gastrointestinal tract; PONSTAN may also decrease the protective effects of low-dose aspirin on the heart and blood vessels

- medicines that prevent blood cells called platelets from clumping together (anti-platelet medicines); combined use with PONSTAN may increase risk of gastrointestinal bleeding
- certain medicines used to treat depression called selective serotonin reuptake inhibitors (SSRIs) ; combined use with PONSTAN may increase risk of gastrointestinal bleeding
- ciclosporin or tacrolimus medicines used to suppress the immune system or prevent organ rejection ; combined use with PONSTAN may increase risk of harmful effects on the kidneys
- insulin or other medicines used to lower blood sugar levels ; combined use with PONSTAN may cause changes in the effects of these medicines
- methotrexate, a medicine used to treat arthritis and certain types of cancer ; combined use with PONSTAN may cause a harmful increase in the levels of this medicine

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

PONSTAN may cause harmful effects to pregnant women and to their unborn baby if taken during pregnancy. PONSTAN may also cause harmful effects in women who are planning to have a baby. PONSTAN should not be used during the first 20 weeks of pregnancy, seek advice from you health care provider if unsure. You must not take PONSTAN at 20 weeks or later of pregnancy.

PONSTAN passes into breast milk and may affect your baby. Do not use PONSTAN if you are breastfeeding.

Driving and using machines

It is not always possible to predict to what extent PONSTAN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PONSTAN affects them. PONSTAN may cause dizziness, drowsiness and blurred vision which could affect the ability to drive or use machines.

PONSTAN contains lactose

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

3. How to take PONSTAN

Do not share medicines prescribed for you with any other person.

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

The usual adult dosage is 2 capsules (500 mg) three times a day with meals. Therapy should not be continued for longer than 7 days.

Your doctor will tell you how long your treatment with PONSTAN will last. If you have the impression that the effect of PONSTAN is too strong or too weak, tell your doctor or pharmacist.

If you take more PONSTAN than you should

It is important to note that seizures or fits, kidney failure, coma, confusion, dizziness and hallucinations have occurred in patients that have taken more PONSTAN than they should.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take PONSTAN

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

4. Possible side effects

PONSTAN can have side effects.

Not all side effects reported for PONSTAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PONSTAN, please consult your health care provider for advice.

If any of the following happens, stop taking PONSTAN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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.
- yellowing of the skin or whites of the eyes (jaundice) along with itching, dark urine and light-coloured stools

These are all very serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- diarrhoea
- nausea with or without vomiting
- stomach pain

Less frequent side effects

- changes in blood counts
- severe allergic reaction

- increase in blood sugar (glucose) levels
- decrease in blood sodium levels
- water retention causing swelling in hands, feet, ankles and legs
- nervousness
- inflammation of brain and spinal cord causing headache, fever and stiff neck
- drowsiness
- headache
- blurred vision
- seizures or fits
- inability to sleep
- eye irritation
- loss of colour vision
- ear pain
- fast or irregular heartbeat
- low blood pressure
- high blood pressure
- difficulty breathing including tightness in chest, wheezing, shortness of breath
- loss of appetite
- heartburn
- gas (wind)
- inflammation of the intestines or colon
- oily stools
- yellowing of the skin or whites of the eyes (jaundice) along with itching, dark urine and light-coloured stools
- inflammation of the liver
- inflammation of the pancreas
- kidney failure
- constipation
- stomach and intestinal problems (inflammation, ulcers, bleeding, rupture in wall of gastrointestinal tract)

- swelling under the skin, especially around face, throat, limbs or genitals
- swelling in the throat
- widespread rash, redness, blistering, pustules or peeling of large areas of skin that may be combined with fever, feeling unwell, or swelling of the mouth, nose, eyes, genitals or lymph nodes
- excessive sweating
- itching
- hives
- face swelling
- kidney disease or kidney failure
- blood in the urine
- painful urination
- protein in the urine
- swelling
- abnormal urine or liver tests

Other side effects

- symptoms of a serious hypersensitivity reaction called DRESS, including skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of the internal organs
- symptoms of a serious skin reaction called generalized bullous fixed drug eruption (GBFDE), caused by allergic reaction to a medicine. It results in widespread, painful and blistering skin lesions that tend to appear in the same locations or over the whole body.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PONSTAN.

5. How to store PONSTAN

- Store all medicines out of reach of children.
- Store PONSTAN in a cool (at or below 25 ºC), dry place.
- Do not take PONSTAN after the expiry date shown on the containers, blisters or cartons.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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 gelatin, lactose and sodium lauryl sulphate.

The capsule shell contains gelatin, indigo carmine (indigotine) (E132), titanium dioxide (E171) and yellow iron oxide (E172).

The printing ink contains black iron oxide (E172).

What PONSTAN looks like and contents of the pack

Yellowish opaque body and light blue opaque top with “Parke-Davis” printed in black on body and cap.

PONSTAN CAPSULES are supplied in white PVC/aluminium blister strips each containing 10 capsules packed into a carton. Each carton contains 20 capsules.

Holder of Certificate of Registration

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