PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PONSTAN® 125 mg PAEDIATRIC SUPPOSITORIES

Mefenamic acid

Sugar free

Read all of this leaflet carefully before your child starts using 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 your child personally and you should not share your child's medicine with other people. It may harm them, even if their symptoms are the same as your child's.

What is in this leaflet

1. What PONSTAN is and what it is used for
2. What you need to know before your child uses PONSTAN
3. How to use 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 suppositories provide pain relief and help reduce fever in children 6 months to 2 years of age.

2. What you need to know before your child uses PONSTAN

Do not use PONSTAN

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

Warnings and precautions

Take special care with PONSTAN

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

- if your child develops 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 using 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 your child has asthma and is sensitive to aspirin
- If your child develops a lower than normal amount of red blood cells (anaemia)
- if your child is dehydrated from loss of fluid or taking water tablets

Some children will need special care from their doctors when they are using PONSTAN and will need testing of blood counts and liver function.

Other medicines and PONSTAN

Always tell your health care provider if your child is 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
- aspirin and other nonsteroidal anti-inflammatory medicine 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

- 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; ombined 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

3. How to use PONSTAN

Do not share medicines prescribed for your child with any other person.

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

Insert one PONSTAN suppository rectally three times a day at intervals of 6 to 8 hours as needed in children 6 months to 2 years of age, weighing not less than 10 kg. The use of paediatric suppositories every 6 to 8 hours for longer than 24 hours is not recommended.

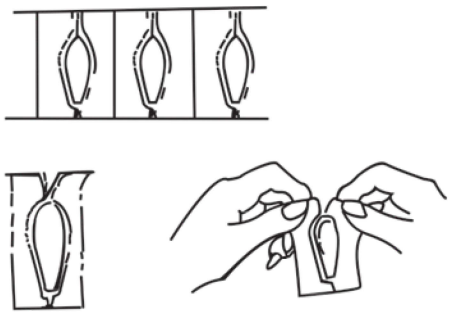
Your doctor will tell you how long your child's treatment with PONSTAN will last. If you have the impression that the effect of PONSTAN is too strong or too weak, tell your doctor or pharmacist.

Instructions for use

This medicine should not be taken orally

1. Remove the outer wrapper/plastic cover from the suppository (see Illustration 1). If the suppository is too soft, chill it before removal from wrapping/plastic cover by placing it under cool running water or in the refrigerator for a few minutes.

Illustration 1



2. Soften the exterior of the suppository slightly by dipping it quickly into some lukewarm water.

3. Lie patient on their side and raise their knee to their chest (see Illustration 2) or support patient in a crawling position (see Illustration 3).

Illustration 2

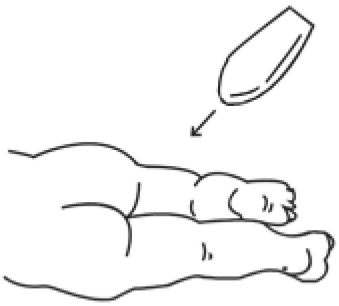
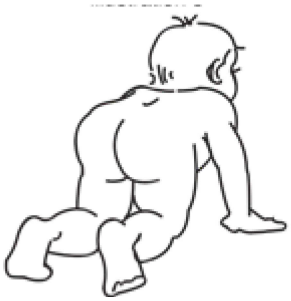


Illustration 3



4. Insert the tapered (pointed) end of the suppository high into the rectum ensuring that it does not slip out. Better retention of suppositories has been found by inserting the suppository with its base (blunt end) foremost.

5. Patient should remain lying down for a few minutes so that the suppository will dissolve in the rectum. The buttocks should be held together for a few minutes.

Rectal suppositories are more effective if they are used when the bowel is empty, therefore, if possible, insert after a bowel movement.

If your child is given more PONSTAN than they should

It is important to note that seizures or fits, kidney failure, coma, confusion, dizziness and hallucinations have occurred in patients that have used 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 give your child PONSTAN

Do not give 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 child's general health worsen or if your child experiences any untoward effects while using 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 in your child:

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.

Tell your doctor if you notice signs of low body temperature in your child such as cool skin, shivering or a low level of energy.

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

Reporting side effects

If your child gets 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 use PONSTAN after the expiry date shown on the package.
- 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 suppository contains 125 mg mefenamic acid.
- The other ingredient is hard fat (Suppocire AML).

What PONSTAN looks like and contents of the pack

Creamy white, bullet-shaped suppositories.

PONSTAN PAEDIATRIC SUPPOSITORIES are supplied in packs of 5.

Holder of Certificate of Registration

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