SCHEDULING STATUS

S3

PONSTEL 250, 250 mg capsules

Mefenamic acid

Contains sugar (lactose monohydrate): 60 mg

PONSTEL FORTE, 500 mg tablets

Mefenamic acid

Sugar free

PONSTEL S, 50 mg/5 mL suspension

Mefenamic acid

Preservative (sodium benzoate): 0,5 % *m/v*

Contains ethanol 96,5 %: 0,025 mL

Contains sugar (sucrose): 1,0 g

Contains sorbitol 70 % solution: 970 mg

Read all of this leaflet carefully before you start taking PONSTEL

- 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.
- PONSTEL 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 PONSTEL is and what it is used for
2. What you need to know before you take PONSTEL
3. How to take PONSTEL
4. Possible side effects
5. How to store PONSTEL
6. Contents of the pack and other information

1. What PONSTEL is and what it is used for

PONSTEL contains mefenamic acid. It belongs to a group of medicines called antipyretics (reduces fever), and anti-inflammatory analgesics (for pain and inflammation).

PONSTEL is indicated to treat pain, swelling and inflammation that are caused due to trauma or wear and tear of the joints or muscles, for a maximum period of 5 days. It is also indicated for primary dysmenorrhoea (cramping pain in the lower abdomen occurring just before or during menstruation), headache, tooth pain, as well as for reducing fevers associated with seizures.

2. What you need to know before you take PONSTEL

Do not take PONSTEL:

- if you are hypersensitive (allergic) to mefenamic acid, or any of the other ingredients of PONSTEL (listed in section 6).
- if you think you may have reacted to any other NSAID (e.g. aspirin, ibuprofen) with sensitivity reactions where symptoms of bronchospasm (coughing or wheezing), allergic rhinitis (itchy, watery eyes and sneezing), or urticaria (skin rash and itching) has occurred. If these reactions have previously occurred with use of other NSAIDs, it is possible that cross-sensitivity can occur and the use of mefenamic acid may also lead to sensitivity reactions,
- if you have heart failure,
- if you have inflammation of the stomach or small intestine, or if you have a history of stomach or intestinal ulceration,
- if you have kidney or liver problems,
- if you suffer from epilepsy (fits/ seizures),
- if you have previously suffered from bleeding of your stomach ulcers, as a result of previous use of PONSTEL or any other NSAID (e.g., aspirin, ibuprofen),
- if you currently suffer from an ulcer, or you have a history where your stomach ulcers have easily reoccurred,
- if you are pregnant, do not use NSAIDs at 20 weeks or later in your pregnancy unless specifically advised to do so by your healthcare professional because these medicines may cause problems in your unborn baby.

Warnings and precautions

Take special care with PONSTEL:

- Stop using PONSTEL if you develop diarrhoea or a skin rash. Severe skin reactions have been reported, some of them can be life-threatening, such as: exfoliative dermatitis (redness and peeling of the skin), Stevens-Johnson syndrome (flu-like symptoms along with a painful skin rash and blistering), epidermal necrolyis (quick progression of severe blistering and peeling). The use of PONSTEL should be stopped at the first appearance of a skin rash, mucosal lesions (abnormal alteration of the mouth surface), or any signs of hypersensitivity,
- if you have a history of high blood pressure and/ or heart failure, as it has been reported that PONSTEL can cause water retention and oedema (swelling). The development of heart failure can be associated with these side-effects especially in patients with other known medical problems,
- if you are an elderly, the risk to develop side-effects affecting the bowels when using NSAIDs such as PONSTEL, are higher. Therefore, you should be carefully monitored for stomach ulcers and bleeding as the possibility exists to develop life-threatening effects,
- when you are using PONSTEL in higher than normal quantities, the risks of developing gastro-intestinal problems (ulceration and bleeding) are higher, especially if you have had ulcers before, or if you are elderly,
- stop using PONSTEL when you experience serious gastrointestinal problems (such as bleeding from the gastrointestinal tract),
- if you have had previous gastrointestinal diseases such as ulcerative colitis (an inflammatory bowel disease that causes inflammation and sores), Crohn's disease (inflammation of your digestive tract), hiatus hernia (when your stomach bulges up into your chest through an opening in your diaphragm), gastroesophageal reflux disease (a type of heartburn) or angiodysplasia (abnormality of the blood vessels within the gastrointestinal (GI) tract),
- if you are dehydrated, due to kidney disease or being an elderly,
- if you have reacted with bronchoconstriction (coughing, wheezing, and shortness of breath) after the use of aspirin,
- it should be taken into account that some results of certain urine tests, can provide a false positive for the presence of bile (digestive fluid produced by the liver and stored in the gallbladder),
- if you have heart failure, a weakened functioning of your kidney or liver, are elderly or if you are currently taking diuretics (water tablets), the risk of suffering from toxic levels of mefenamic acid is higher,

- if you have diabetes, high cholesterol, high blood pressure or if you are smoking: the risk of developing heart diseases are higher and careful consideration should be taken before the use of mefenamic acid,
- tell your doctor or healthcare provider if you are pregnant or plan to become pregnant. Taking NSAIDs at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of your pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs around 30 weeks of pregnancy or later.
- if you develop a fever, skin rash, swelling of the lymph nodes and/or swelling of the face. This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

Children

Do not give PONSTEL to small children (younger than 6 months) as it is unlikely to be safe.

Other medicines and PONSTEL:

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

- blood thinning tablets (e.g., warfarin) may delay the formation of clots and the use with mefenamic acid may increase the risk of bleeding. The use thereof should be reviewed and your doctor must monitor you more closely,
- selective serotonin reuptake inhibitors (SSRIs) (medicines used in the treatment of depression) and anti-platelet medicines (medicines that makes your blood less sticky), can cause an increased risk of stomach or intestine bleeding,
- lithium (a medicine used to treat moods and certain types of depression) can build up in your blood and the increased concentrations can cause lithium toxicity,
- other anti-inflammatory medicines such as NSAIDs (e.g., aspirin, ibuprofen, etc.) can intensify stomach or bowel side effects,
- corticosteroids such as prednisone and cortisone (medicines that lowers the inflammation in the body), increase the risk of developing side-effects affecting the bowels.

PONSTEL with food and drink and alcohol

PONSTEL should be taken during meals to reduce gastric irritation.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before taking PONSTEL.

No data on the influence of fertility is available.

Driving and using machines

It is not always possible to predict to what extent PONSTEL may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which PONSTEL affects you.

PONSTEL 250 contains lactose monohydrate

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

PONSTEL S contains sodium benzoate

This medicine contains 5 mg sodium benzoate in each 10 mL which is equivalent 0,5 % *m/v*. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in new-born babies (up to 4 weeks old).

PONSTEL S contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 5 mL, that is to say essentially ‘sodium-free’.

PONSTEL S contains ethanol

This medicine contains 0,025 mL of alcohol (ethanol) in each unit volume which is equivalent to 5 % *v/v*. The small amount of alcohol in this medicine will not have any noticeable effects.

PONSTEL S contains sucrose

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

PONSTEL S contains sorbitol

This medicine contains 970 mg sorbitol in each 5 mL which is equivalent to 19,4 % *m/v*. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

3. How to take PONSTEL

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

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

Use the lowest effective dose for the shortest possible duration of treatment. Therapy should not be continued for longer than 7 days.

The usual dose is:

Adults: 500 mg three times per day

In menorrhagia (menstrual bleeding lasting for longer than 7 days) the dosage is 500 mg three times a day beginning with the start of menstrual period and continue using until the menstrual flow has stopped or for no longer than the next five days.

In primary dysmenorrhoea (menstrual cramps or pain) the dosage is 500 mg three times a day, start the use of PONSTEL at the beginning of period pain and continue the use for up to three days of experiencing symptoms.

The usual dose is:

Children (6 months and older): 25 mg/kg of body weight daily, in divided doses, or:

- 6 months to 1 year: One medicine measureful (5 mL)
- 2 to 4 years: Two medicine measureful (10 mL)
- 5 to 8 years: Three medicine measuresful (15 mL)
- 9 to 12 years: Four medicine measuresful (20 mL)

The doses may be repeated as necessary, up to three times daily.

Gastric irritation may be reduced by taking medication during meals.

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

If you take more PONSTEL than you should

Mefenamic acid has shown to cause tonic-clonic (grand mal) convulsions (fits) in overdosage. Dyskinesia (involuntary movement that you cannot control), sudden kidney failure and coma (state of prolonged unconsciousness) have been reported.

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

Overdose of PONSTEL has led to deaths. Treatment is symptomatic and supportive.

If you forget to take a dose of PONSTEL

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

If you stop taking PONSTEL

No information available.

4. Possible side effects

PONSTEL can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- hypersensitivity skin reactions including urticaria (skin itching, flushed or pale skin), coughing or wheezing (signs of bronchospasm), fainting (signs of a life threatening allergic reaction),
- allergic reactions which can include flu-like symptoms along with a skin rash, itching, painful red areas, peeling or blistering, swollen face, lips, hands or fingers (Stevens-

Johnson's syndrome).

These are all very serious side effects. If you have them, you may have had a serious reaction to PONSTEL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain,
- changes in the way your heart beats, for example, if you notice it is beating faster,
- difficulty breathing,

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

Tell your doctor if you notice any of the following:
Side effects:

- changes in the levels of certain components of your blood (haemolytic anaemia, agranulocytosis, decreased haematocrit, eosinophilia, aplastic anaemia, leukopenia, pancytopenia, thrombocytopenic purpura and bone marrow aplasia),
- raised levels of liver enzymes in the blood,
- swelling of the skin or face (angioedema or facial oedema),
- swelling of the larynx (face or throat),
- severe blistering and peeling of the skin (epidermal necrolyis),
- erythema multiforme (painful or itchy skin eruption),
- sweating,
- urticaria (skin rash and itching),
- exfoliative dermatitis (redness and peeling of the skin),
- inability to handle the intake of sugars (glucose intolerance) specifically in diabetic patients,
- headache,
- tiredness or dizziness,
- nervousness,
- sleeplessness,
- convulsions (fits),
- visual disturbances,
- ear pain,

- changes in blood pressure,
- changes in bowel movements (diarrhoea),
- nausea and/ or vomiting,
- stomach pain,
- ulcers or bleeding of the stomach or intestines,
- decrease in appetite,
- heartburn or feeling of bloatedness,
- indigestion,
- infection or inflammation of the bowels (enterocolitis),
- steatorrhoea (oily stools),
- inflammation of the liver or pancreas,
- cholestatic jaundice (dark urine and light-coloured bowel movements),
- lower gut disorders (inflammatory bowel disease or Crohn's disease),
- ulcerative stomatitis (mouth ulcers with sore breaks in the skin),
- melaena or haematemesis (bleeding in the digestive tract),
- fever, skin rash, swelling of the lymph nodes and/or swelling of the face (also known as DRESS),
- kidney problems or hepatorenal syndrome (progressive kidney failure),
- dysuria (pain or discomfort when urinating),
- blood in the urine.

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

Reporting of side effects

If you get 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 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 PONSTEL.

5. How to store PONSTEL

Store all medicines out of reach of children.

Store in a cool (at or below 25 ºC), dry place.

Keep the blisters in outer carton until required for use.
Keep bottle tightly closed.
PONSTEL FORTE to be protected from direct sunlight.
Do not use after the expiry date stated on the label / carton / bottle.
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 PONSTEL contains

The active substance is mefenamic acid.
PONSTEL 250: Each capsule contains 250 mg mefenamic acid.
PONSTEL FORTE: Each tablet contains 500 mg mefenamic acid.
PONSTEL S: Each 5 mL suspension contains mefenamic acid 50 mg / 5mL.

The other ingredients in PONSTEL 250 are D & C yellow No. 10 (CI 47005), FD & C red No. 3 (CI 45430), gelatin, lactose monohydrate, titanium dioxide (CI 77891).

The other ingredients in PONSTEL FORTE are calcium stearate, colloidal anhydrous silica (silicon dioxide), hydroxypropyl cellulose, microcrystalline cellulose, starch corn (maize starch), sodium lauryl sulphate, spectracol quinoline (PLK0013) (Colour D&C yellow No. 10 lake (CI 47005), spectracol erythrosine lake (805005) FD&C red No.3 lake (CI 45430).

The other ingredients in PONSTEL S are caramel 48000 (clarkes), carboxymethylcellulose sodium 7MF, ethanol 96,5 %, flavor anise mint LR3072A, flavor butter toffee 78185-33, glucono delta lactone, hydrochloric acid AR 37 %, povidone K29-32, purified water, sodium benzoate, sodium hydroxide B.P, sorbitol 70 % solution (non-crystallising), sugar granulated (sucrose), veegum HV.

What PONSTEL looks like and contents of the pack

PONSTEL 250:
Size '1' hard gelatin capsules with an ivory opaque body and cap containing a white to slightly off-white powder.
Content of the packaging:
250 mg capsules in containers of 100's and 250's, and blister packs of 20's.

- **100's pack:** White cylindrically shaped polypropylene securitainer (49 x 75 mm) with a round white LDPE closure.
- **250's pack:** White cylindrically shaped polypropylene securitainer (62 x 152 mm) with a round white LDPE Closure.
- **250's pack:** White cylindrical shaped high density polyethylene (HDPE) container (475 mL, 53 x 450 cc) with screw cap with an inside wad seal.
- **20's pack:** Clear, transparent, non-toxic well thermo formable, food grade PVC film on printed aluminium foil with VMCH coating (dull side printing).

PONSTEL FORTE:
Buff-coloured, round, biconvex tablets.
Content of the packaging:
500 mg tablets in containers of 50's.

- **50's Blister pack**: Clear, transparent, non-toxic, well thermo formable, food grade PVC film on aluminium foil with vmch coating on bright side (dull side printing).
- **50's Securitainer pack:** White or grey polypropylene securitainer (0205), 49 mm LDPE closure and cotton wool balls as wadding.
- **50's HDPE container:** 160mL (35 x 150) white colour cylindrical screw type high density polyethylene (HDPE) container with a white colour HDPE screw cap with induction seal Wad.

PONSTEL S:
A creamy, light caramel coloured, uniform suspension with a butter toffee and anise mint odour and taste.
Content of the packaging:
Suspension in bottles of 100 ml, 200 ml and 2,5 L.
PONSTEL S, is packed using the following packaging materials:

- 100 mL or 200 mL amber glass bottles with a 28 mm white polypropylene cap with liner.
- 2,5 L rectangular amber HDPE bottle with a utility thread finish with a 3,15 mm white polypropylene cap with liner.

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