SCHEDULING STATUS: S3

PROPRIETARY NAMES (AND DOSAGE FORMS):

PONSTAN (CAPSULES)

PONSTAN FORTE (TABLET)

PONSTAN (SUSPENSION)

PONSTAN (PAEDIATRIC SUPPOSITORIES)

COMPOSITION:

PONSTAN CAPSULES:	250 mg mefenamic acid per capsule
PONSTAN FORTE:	500 mg mefenamic acid per tablet
PONSTAN SUSPENSION:	50 mg mefenamic acid in each 5 ml medicine measure Alcohol 0,5 % v/v Sucrose 20 % m/v Preservative: Sodium benzoate 0,5 % m/v
PONSTAN PAEDIATRIC SUPPOSITORIES:	125 mg mefenamic acid per suppository

PHARMACOLOGICAL CLASSIFICATION:

A 2.7 Anti-pyretic or anti-pyretic and anti-inflammatory analgesics

PHARMACOLOGICAL ACTION:

Mefenamic acid has analgesic, anti-inflammatory and anti-pyretic properties.

The pharmacological activity of mefenamic acid may be due in part to its ability to inhibit the synthesis of prostaglandins. Mefenamic acid also inhibits the action of exogenous prostaglandins on uterine muscle, uterine tube contraction and ovarian cyclic AMP and progesterone formation in animal models.

Pharmacokinetic Properties:

Absorption

Mefenamic acid is well absorbed from the gastro-intestinal tract. Peak plasma concentrations occur in about 2 to 4 hours, with a half-life of 2 to 4 hours. Plasma levels are proportional to dose, following multiple doses, with no drug accumulation.

Distribution

Mefenamic acid is extensively bound to plasma proteins.

Elimination

Over 50% of the dose may be recovered in the urine as unchanged drug or conjugated metabolites.

INDICATIONS:

S2: For the symptomatic treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. For the symptomatic treatment of primary dysmenorrhoea for a maximum period of 3 days.

S3: For the relief of mild to moderate pain in acute and chronic conditions including pain of traumatic, arthritic or muscular origin; primary dysmenorrhoea, headache and dental pain.
It is also indicated as an anti-pyretic in febrile conditions.

PONSTAN reduces blood loss in menorrhagia where the menorrhagia is due to ovulatory dysfunctional bleeding. Uterine and other pathology should first be excluded before prescribing PONSTAN for this indication.
PONSTAN Suppositories are indicated for the symptomatic treatment of pain and fever in children 6 months to 2 years when oral therapy is not possible.

CONTRAINDICATIONS:

Sensitivity to mefenamic acid and other nonsteroidal anti-inflammatory agents with prostaglandin-synthetase inhibiting activity. Because the possibility exists for cross-sensitivity among nonsteroidal anti-inflammatory agents, PONSTAN should not be given to patients in whom these drugs induce symptoms of bronchospasm, allergic rhinitis, or urticaria.
PONSTAN is contra-indicated in patients with chronic inflammation of either the upper or lower gastro-intestinal tract, in patients with a history of peptic and/or intestinal ulceration, patients with impaired renal or hepatic function, and epilepsy.

WARNINGS AND SPECIAL PRECAUTIONS:

If diarrhoea or skin rash appear, PONSTAN should be discontinued immediately.
Blood counts and liver function should be monitored during long-term therapy.
PONSTAN may enhance the effects of oral anticoagulants (See Interactions).
Diarrhoea may occur within 24 hours following usual analgesic dosage. When diarrhoea occurs, the medication should be discontinued immediately. Temporary lowering of the white

blood cell count has occurred but does not appear to be dose-related. Blood counts should be performed at regular intervals during long-term administration. Serious gastro-intestinal toxicity such as bleeding, ulceration, and perforation can occur at any time with or without warning symptoms.

Elderly or debilitated patients are more likely to experience gastro-intestinal events.

Haemolytic anaemia may develop in patients taking PONSTAN. While this condition is generally reversible, death due to PONSTAN-associated haemolytic anaemia has been reported. Liver function tests must be carried out regularly to monitor elevation of enzymes and bilirubin.

Because of the possibility of cross-sensitivity due to structural relationships which exist among nonsteroidal anti-inflammatory medicines, acute allergic reactions may be more likely to occur in patients who have exhibited allergic reactions to these compounds.

Occurrence of rash is a definite reason for stopping medication because exfoliative dermatitis has been reported on continued use after development of a rash.

Caution should be exercised in the administration of PONSTAN to patients suffering from dehydration and/or renal disease, particularly the elderly.

Bronchoconstriction may occur with PONSTAN in asthmatic patients with aspirin sensitivity.

PONSTAN and its metabolites may give a false positive reaction to certain urine tests for the presence of bile.

Toxicity has also been seen in patients with prerenal conditions leading to a reduction in renal blood flow or blood volume. Patients at greatest risk are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics, and the elderly.

Effects on Ability to Drive and Operate Machinery:

The effect of PONSTAN on the ability to drive or operate machinery has not been systematically evaluated.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:

Anticoagulants: Patients receiving an anticoagulant drug concurrently with PONSTAN have had a prolongation of prothrombin time. PONSTAN is contraindicated for patients taking an anticoagulant drug if careful and continuous monitoring of the levels of prothrombin and Factors VII, IX and X is not available.

Lithium: Patients receiving lithium concurrently with nonsteroidal anti-inflammatory drugs including PONSTAN, have produced an elevation of plasma lithium levels and a reduction in renal lithium clearance. Thus, when PONSTAN and lithium are administered concurrently, patients should be observed carefully for signs of lithium toxicity.

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

Mefenamic acid may be present in breast milk therefore PONSTAN should not be taken by nursing mothers.

DOSAGE AND DIRECTIONS FOR USE:

Gastric irritation may be reduced by taking medication during meals. Therapy should not be continued for longer than 7 days.

Adults: 500 mg three times per day.

In menorrhagia the dosage is 500 mg three times a day beginning with the onset of menstrual flow and continuing for five days or until cessation of flow, whichever is less.

In primary dysmenorrhoea the dosage is 500 mg three times a day commencing at the onset of period pain and continued for up to three days while the symptoms persist.

Suspension:

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 measuresful (10 ml)

5 to 8 years : Three medicine measuresful (15 ml)

9 to 12 years : Four medicine measuresful (20 ml)

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

Paediatric Suppositories:

Children 6 months to 2 years, weighing not less than 10 kg: One suppository to be inserted rectally three times a day at intervals of 6 to 8 hours as needed.

One 125 mg suppository is equivalent to approximately 60 mg (6 ml) PONSTAN suspension.

The use of paediatric suppositories every 6 to 8 hours for longer than 24 hours is not recommended.

SIDE-EFFECTS :

System Organ Class	Frequency	Adverse Event
Gastrointestinal	Frequent	Diarrhoea Nausea with or without vomiting Abdominal pain
	Less frequent	Anorexia Pyrosis Flatulence Enterocolitis Colitis Steatorrhoea Cholestatic jaundice Hepatitis Pancreatitis Hepatorenal syndrome Mild hepatic toxicity Constipation Peptic ulceration with or without gastrointestinal haemorrhage
Blood and lymphatic system disorders	Less frequent	Haemolytic anemia Decreased hematocrit Leukopenia Eosinophilia Thrombocytopenia or thrombocytopenic purpura Agranulocytosis Pancytopenia Aplastic anemia Bone marrow aplasia
Immune system disorders	Less frequent	Anaphylaxis
Metabolism and nutrition disorders	Less frequent	Glucose intolerance in diabetic patients Hyponatremia
Psychiatric disorders	Less frequent	Nervousness
Nervous system disorders	Less frequent	Drowsiness Dizziness Headache Visual disturbances Convulsions Insomnia
Ear and labyrinth disorders	Less frequent	Ear pain
Cardiac disorders	Less frequent	Palpitations
Vascular disorders	Less frequent	Hypotension
Respiratory, thoracic and mediastinal disorders	Less frequent	Asthma Bronchospasm Dyspnoea
Skin and subcutaneous tissue disorders	Less frequent	Angioedema Oedema of the larynx Stevens-Johnson syndrome Lyell's syndrome (toxic epidermal

		necrolysis) Erythema multiforme Perspiration Pruritis Urticaria Rash Facial oedema
Renal and urinary disorders	Less frequent	Renal failure Papillary necrosis Acute interstitial nephritis with haematuria Dysuria Proteinuria Allergic glomerulonephritis
	Occasional	Nephrotic syndrome

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See "Side-effects ".

PONSTAN has a marked tendency to induce tonic-clonic (grand mal) convulsions in overdosage. Dyskinesia, acute renal failure and coma have been reported. Overdose has led to fatalities.

Treatment is symptomatic and supportive. Following accidental overdosage, the stomach should be emptied immediately by inducing emesis or by gastric lavage followed by administration of activated charcoal. Vital functions should be monitored and supported. Haemodialysis is of little value since mefenamic acid and its metabolites are firmly bound to plasma proteins.

IDENTIFICATION:

PONSTAN CAPSULES: Ivory opaque body and aqua blue opaque cap, imprinted "Parke-Davis" and "Ponstan 250" or yellowish opaque body and light blue opaque top. “Parke-Davis” printed in black on body and cap.

PONSTAN FORTE: Buff-coloured, round, biconvex tablets or pale yellow, oval, biconvex, film-coated tablets.

PONSTAN SUSPENSION: A creamy, opaque, off-white suspension with a pleasant characteristic odour and taste.

PONSTAN PAEDIATRIC SUPPOSITORIES: Creamy white, bullet-shaped suppositories.

PRESENTATION:

PONSTAN CAPSULES:	Containers of 100 and 250, and blisters of 12 capsules or white PVC/Aluminium blister strips each containing 10 capsules packed into a carton. Each carton may contain either 10, 20, 30, 50 or 100 capsules.
PONSTAN FORTE:	Containers of 50 tablets or white PVC/Aluminium blister strips each containing 10 tablets packed into a carton. Each carton may contain either 10, 20, 30, 50 or 100 tablets.
PONSTAN SUSPENSION:	Bottles of 100 ml, 200 ml and 2,5 L

PONSTAN PAEDIATRIC SUPPOSITORIES: Packs of 5

STORAGE INSTRUCTIONS:

Store in a cool (at or below 25 ºC), dry place. PONSTAN FORTE to be protected from direct sunlight.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:

PONSTAN CAPSULES:	B/2.7/560
PONSTAN FORTE:	H/2.7/13
PONSTAN SUSPENSION:	B/2.7/561
PONSTAN PAEDIATRIC SUPPOSITORIES:	27/2.7/0561

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Pfizer Laboratories (Pty) Ltd
85 Bute Lane
Sandton
2196
South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

1. Last Council Approval: 6 May 2005
2. Compliance with Regulation 9 &10: 15 December 2016

BOTSWANA: S2

Capsules: Reg. No.: B9321805

Suspension: Reg. No.: B9321815

NAMIBIA: S2

Capsules: Reg. No.: 04/2.7/1237

Paediatric Suppositories: Reg. No.: 04/2.7/1238

Suspension: Reg. No.: 04/2.7/1239

ZAMBIA: P

Capsules: Reg. No.: 120/027

Paediatric Suppositories: Reg. No.: 120/028

ZIMBABWE: PP

Capsules: Reg. No. 74/2.1/261

Suspension: Reg. No. 74/2.1/262