PT. PFIZER INDONESIA
Local Product Document

Generic Name: Mefenamic acid
Trade Name: PONSTAN
CDS Effective Date: February 17, 2022
Supersedes: July 05, 2021

Cardiovascular Risk

- NSAIDs may cause an increased risk of serious cardiovascular (CV) thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. The relative increase of this risk appears to be similar in those with or without known CV disease or CV risk factors. However, patients with known CV disease or CV risk factors may be at greater risk in terms of absolute incidence, due to their increased rate at baseline (see **section WARNINGS AND PRECAUTIONS**).
- PONSTAN is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery (see **section WARNINGS AND PRECAUTIONS**).

Gastrointestinal Risk

- NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events (see **section WARNINGS AND PRECAUTIONS**).

DRUG PRESENTATION

Film-coated tablet. An elliptical, smooth, yellow film coated tablet embossed with P-D logo on one side and bisect line on the other side.

COMPOSITION

Film-coated tablet: Mefenamic acid 500 mg.

DRUG LIST CLASSIFICATION

Prescription drug.

ACTIONS

Mefenamic acid is non-steroid anti-inflammation that act by inhibiting prostaglandin synthesis process in body tissue by inhibiting cyclo-oxygenase enzymes therefore it has analgesic, anti-inflammation, and anti-pyretic effects.

METABOLISM

Mefenamic acid metabolism is predominantly mediated via cytochrome P450 (CYP) 2C9 in the liver. Patients who are known or suspected to be poor CYP2C9 metabolizers based on previous history/experience with other CYP2C9 substrates should be administered mefenamic acid with caution as they may have abnormally high plasma levels due to reduced metabolic clearance.

ELIMINATION
Following a single oral dose, 52% of a dose is recovered from the urine, 6% as mefenamic acid, 25% as metabolite I and 21% as metabolite II. Assay of stools over a 3-day period accounted for 10% - 20% of the dose, chiefly as unconjugated metabolite II.

USAGE
Oral

INDICATIONS
Mefenamic acid is indicated for relief of mild to moderate pain in:
- Rheumatoid arthritis
- Osteoarthritis
- Muscular, traumatic, dental pain
- Headache
- Post-operative, postpartum
- Primary dysmenorrhea
- Premenstrual syndrome

CONTRAINDICATIONS
- Hypersensitivity to mefenamic acid or any components of this product.
- Patient experiencing bronchospasm, allergic rhinitis, and urticaria when treated with acetyl salicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).
- Patient with active ulceration or chronic inflammation of either the upper or lower gastrointestinal tract.
- Patients with pre-existing renal disease.

Treatment of peri-operative pain in the setting of CABG surgery.

Patients with severe renal and hepatic failure.

Patients with severe heart failure.

DOSAGE AND ADMINISTRATION
Undesirable effects may be minimized by using the minimum effective dose for the shortest duration necessary to control symptoms.

The oral dosage form of mefenamic acid may be taken with food if gastrointestinal upset occurs.

Mild to moderate pain in adults and adolescents over 14 years of age: 500 mg three times daily.

Dysmenorrhea: 500 mg three times daily, to be administered at the onset of menstrual pain and continued while symptoms persist according to the judgement of the physician.

Premenstrual syndrome: 500 mg three times daily, starting with the onset of symptoms and continued until the anticipated cessation of symptoms according to the judgement of the physician.

Use in the Elderly
Impairment of renal function, sometimes leading to acute renal failure, has been reported. Elderly or debilitated patients seem unable to tolerate ulceration or bleeding as well as some other individuals; most spontaneous reports of fatal gastrointestinal events are in this patient population. (see **section WARNINGS AND PRECAUTIONS** – Gastrointestinal (GI) Effects).

UNDESIRABLE EFFECTS
Blood and lymphatic system disorders: Agranulocytosis, aplastic anemia, autoimmune hemolytic anemia*, bone marrow hypoplasia, decreased hematocrit, eosinophilia, leukopenia, pancytopenia and thrombocytopenic purpura, platelet aggregation inhibition.

Immune system disorders: Anaphylaxis.

Metabolism and nutrition disorders: Glucose intolerance in diabetic patients, hyponatremia, fluid retention.

Psychiatric disorders: Nervousness.

Nervous system disorders: Aseptic meningitis, blurred vision, convulsions, dizziness, drowsiness, headache, and insomnia.

Eye disorders: Eye irritation, reversible loss of color vision.

Ear and labyrinth disorders: Ear pain.

Cardiac disorders: Palpitation.

Vascular disorders: Hypotension, hypertension.

Respiratory, thoracic, and mediastinal disorders: Asthma, dyspnea.

Gastrointestinal disorders: Gastrointestinal inflammation, gastrointestinal hemorrhage, gastrointestinal ulcer, gastrointestinal perforation.

The most frequently reported side effects associated with mefenamic acid involve the gastrointestinal tract. Diarrhea appears to be the most common side effect and is usually dose-related. It generally subsides on dosage reduction, and rapidly disappears on termination of therapy. Some patients may not be able to continue therapy.

The following are the most common gastrointestinal side effects: abdominal pain, diarrhea, and nausea with or without vomiting.

Less frequently reported gastrointestinal/hepatobiliary side effects include: Anorexia, cholestatic jaundice, colitis, constipation, enterocolitis, flatulence, gastric ulceration with and without hemorrhage, mild hepatic toxicity, hepatitis, hepatorenal syndrome, pyrosis, pancreatitis, and steatorrhea.

Skin and subcutaneous tissue disorders: Angioedema, edema of the larynx, erythema multiforme, facial edema, Lyell's syndrome (toxic epidermal necrolysis), perspiration, pruritus, rash, Stevens-Johnson syndrome, urticaria, and dermatitis exfoliative.

Renal and urinary disorders: Dysuria, hematuria, renal failure including papillary necrosis and tubulointerstitial nephritis, glomerulonephritis, nephrotic syndrome.

General disorders and administration site conditions: Edema

Investigations: Urobilinogen urine (false-positive), liver function test abnormal

Pediatric patients
General disorders and administration site conditions: Hypothermia.

*Reports are associated with ≥12 months of mefenamic acid therapy and the anemia is reversible with discontinuation of therapy.

WARNINGS AND PRECAUTIONS
The use of mefenamic acid with concomitant systemic non-aspirin NSAIDs including cyclooxygenase-2 (COX-2) inhibitors should be avoided. Concomitant use of a systemic NSAID and another systemic NSAID may increase frequency of gastrointestinal ulcers and bleeding.

Cardiovascular Thrombotic Events
Clinical trials of several COX-2 selective and non-selective NSAIDs of up to three years duration have shown an increase risk of serious CV thrombotic events, myocardial infarction, and stroke, which can be fatal.

All NSAIDs, both COX-2 selective and non-selective, may have a similar risk. Patients with known CV disease or risk factors for CV disease may be at greater risk. To minimize the potential risk for an adverse CV event in patients treated with an NSAID, the lowest effective dose should be used for the shortest duration possible. Physicians and patients should remain alert for the development of such events, even in the absence of previous CV symptoms. Patients should be informed about the signs and/or symptoms of serious CV events and the steps to take if they occur.

There is no consistent evidence that concurrent use of acetyl salicylic acid mitigates the increased risk of serious CV thrombotic events associated with NSAID use. The concurrent use of acetyl salicylic acid and an NSAID does increase the risk of serious GI events (see **section WARNINGS AND PRECAUTIONS, Gastrointestinal (GI) Effect - Risk of GI Ulceration, Bleeding, and Perforation**).

Two large, controlled, clinical trials of a COX-2 selective NSAID for the treatment of pain in the first 10-14 days following CABG surgery found an increased incidence of myocardial infarction and stroke (see **section CONTRAINDICATIONS**).

Hypertension
NSAIDs, including PONSTAN can lead to onset of new hypertension or worsening of pre-existing hypertension, either of which may contribute to the increased incidence of CV events. Patients taking thiazides or loop diuretics may have impaired response to these

therapies when taking NSAIDs. NSAIDs, including PONSTAN, should be used with caution in patients with hypertension. Blood pressure (BP) should be monitored closely during the initiation of NSAID treatment with PONSTAN and throughout the course of therapy.

Congestive Heart Failure and Edema
Fluid retention and edema have been observed in some patients taking NSAIDs, including PONSTAN. PONSTAN should be used with caution in patients with fluid retention or heart failure.

Gastrointestinal (GI) Effects - Risk of GI Ulceration, Bleeding, and Perforation
NSAIDs, including PONSTAN, can cause serious gastrointestinal events including, inflammation, bleeding, ulceration, and perforation of the stomach, small intestine or large intestine, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with NSAIDs. Only one in five patients, who develop a serious upper GI adverse event on NSAID therapy, is symptomatic. Upper GI ulcers, gross bleeding, or perforation caused by NSAIDs occur in approximately 1% of patients treated for 3-6 months, and in about 2%-4% of patients treated for one year. These trends with longer duration of use, increasing the likelihood of developing a serious GI event at some time during the course of therapy. However, even short-term therapy is not without risk.

NSAIDs should be prescribed with extreme caution in patients ingesting alcohol or patients with a prior history of ulcer disease or gastrointestinal bleeding. Patients with a *prior history of peptic ulcer disease and/or gastrointestinal bleeding* and who use NSAIDs, have a greater than 10-fold higher risk for developing a GI bleed compared to patients with neither of these risk factors. Other factors that increase the risk for GI bleeding in patients treated with NSAIDs include concomitant use of oral corticosteroids, antiplatelet drugs (such as aspirin), anticoagulants or selective serotonin reuptake inhibitors, longer duration of NSAID therapy, smoking, use of alcohol, older age, and poor general health status. Most spontaneous reports of fatal GI events are in elderly or debilitated patients and therefore, special care should be taken in treating this population.

To minimize the potential risk for an adverse GI event, in patients treated with NSAIDs, the lowest effective dose should be used for the shortest possible duration. Patients and physicians should remain alert for signs and symptoms of GI ulceration and bleeding during NSAID therapy and promptly initiate additional evaluation and treatment if a serious GI adverse event is suspected. This should include discontinuation of the NSAID until a serious GI adverse event is ruled out. For high-risk patients, alternate therapies that do not involve NSAIDs should be considered.

Skin Reactions
Serious skin reactions, some of them fatal, including drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs, including mefenamic acid. Patients appear to be at highest risk for these events early in the course of therapy, the onset of the event occurring in the majority of cases within the first month of treatment. Mefenamic acid should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Renal Effects

In rare cases, NSAIDs, including mefenamic acid, may cause interstitial nephritis, glomerulitis, papillary necrosis, and the nephrotic syndrome. NSAIDs inhibit the synthesis of renal prostaglandin which plays a supportive role in the maintenance of renal perfusion in patients whose renal blood flow and blood volume are decreased. In these patients, administration of an NSAID may precipitate overt renal decompensation, which is typically followed by recovery to pretreatment state upon discontinuation of NSAID therapy. Patients at greatest risk of such a reaction are those with congestive heart failure, liver cirrhosis, nephrotic syndrome, overt renal disease, and the elderly. Such patients should be carefully monitored while receiving NSAID therapy.

Discontinuation of NSAID therapy is typically followed by recovery to the pre-treatment state. Since mefenamic acid metabolites are eliminated primarily by the kidneys, the drug should not be administered to patients with significantly impaired renal function.

Laboratory Tests
A false-positive reaction for urinary bile, using the diazo tablet test, may result following mefenamic acid administration. If biliuria is suspected, other diagnostic procedures, such as the Harrison spot test, should be performed.

Hematologic Effects
Mefenamic acid can inhibit platelet aggregation and may prolong prothrombin time in patients on warfarin therapy (see **section DRUG INTERACTIONS**).

Hepatic Effects
Borderline elevations of one or more liver function tests may occur in some patients receiving mefenamic acid therapy. These elevations may progress, may remain essentially unchanged, or may be transient with continued therapy. A patient with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, should be evaluated for evidence of the development of a more severe hepatic reaction while on therapy with mefenamic acid. If abnormal liver tests persist or worsen, if clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur, mefenamic acid should be discontinued.

Use with Oral Anticoagulants
The concomitant use of NSAIDs, including mefenamic acid, with oral anticoagulants increases the risk of GI and non-GI bleeding and should be given with caution. Oral anticoagulants include warfarin/coumarin-type and novel oral anticoagulants (e.g., apixaban, dabigatran, rivaroxaban). Anticoagulation/INR should be monitored in patients taking a warfarin/coumarin-type anticoagulant (see **section DRUG INTERACTIONS**).

Fertility, Pregnancy, and Lactation
Fertility
Based on the mechanism of action, the use of NSAIDs may delay or prevent rupture of ovarian follicles, which has been associated with reversible infertility in some women. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of NSAIDs, including mefenamic acid should be considered.

Pregnancy
Since there are no adequate and well-controlled studies in pregnant women, this drug should be used only if the potential benefits to the mother justify the possible risks to the

fetus. It is not known if mefenamic acid or its metabolites cross the placenta. However, because of the effects of drugs in this class (i.e., inhibitors of prostaglandin synthesis) on the fetal CV system (e.g., premature closure of the ductus arteriosus), the use of mefenamic acid in pregnant women is not recommended and should be avoided during the third trimester of pregnancy. Mefenamic acid inhibits prostaglandin synthesis which may result in prolongation of pregnancy and interference with labor when administered late in the pregnancy. Women on mefenamic acid therapy should consult their physician if they decide to become pregnant.

Inhibition of prostaglandin synthesis might adversely affect pregnancy. Data from epidemiological studies suggest an increased risk of spontaneous abortion after use of prostaglandin synthesis inhibitors in early pregnancy. In animals, administration of prostaglandin synthesis inhibitors has been shown to result in increased pre- and post-implantation loss.

If used during second or third trimester of pregnancy, NSAIDs may cause fetal renal dysfunction which may result in reduction of amniotic fluid volume or oligohydramnios in severe cases. Such effects may occur shortly after treatment initiation and are usually reversible upon discontinuation. Pregnant women on mefenamic acid should be closely monitored for amniotic fluid volume.

Lactation
Trace amounts of mefenamic acid may be present in breast milk and transmitted to the nursing infant. Therefore, mefenamic acid should not be taken by nursing mothers.

EFFECT ON ABILITY TO DRIVE AND USE MACHINES
Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

DRUG INTERACTIONS
Acetylsalicylic acid: Mefenamic acid interferes with the anti-platelet effect of low-dose aspirin, and thus may interfere with aspirin's prophylactic treatment of CV disease.

Anticoagulants: Mefenamic acid has been shown to displace warfarin from protein binding sites, and may enhance the response to oral anticoagulants. Therefore, concurrent administration of mefenamic acid with oral anticoagulant drugs requires frequent prothrombin time monitoring.

Anti-hypertensives including diuretics, angiotensin-converting enzyme (ACE) inhibitors , angiotensin II antagonists (AIIA) and beta-blockers: NSAIDs can reduce the efficacy of diuretics and other antihypertensive drugs, including ACE inhibitors, AIIA, and beta blockers.

In patients with impaired renal function (e.g., dehydrated patients or elderly patients with compromised renal function), the co-administration of an ACE inhibitor or an AIIA and/or diuretics with a cyclo-oxygenase inhibitor can increase the deterioration of the renal function, including the possibility of acute renal failure, which is usually reversible. The occurrence of these interactions should be considered in patients taking mefenamic acid with an ACE inhibitor or an AIIA and/or diuretics.

Therefore, the concomitant administration of these drugs should be done with caution, especially in elderly patients. Patients should be adequately hydrated and the need to monitor the renal function should be assessed in the beginning of the concomitant treatment and periodically thereafter.

Corticosteroids: Increased risk of gastrointestinal ulceration or bleeding.

Cyclosporine: Because of their effect on renal prostaglandins, NSAIDs such as mefenamic acid may increase the risk of nephrotoxicity with cyclosporine.

Hypoglycemic agents: There have been reports of changes in the effects of oral hypoglycemic agents in the presence of NSAIDs. Therefore, mefenamic acid should be administered with caution in patients receiving insulin or oral hypoglycemic agents.

Lithium: Mefenamic acid has produced an elevation of plasma lithium levels and a reduction in renal lithium clearance. Thus, when mefenamic acid and lithium are administered concurrently, patients should be observed carefully for signs of lithium toxicity.

Methotrexate: Caution is advised when methotrexate is administered concurrently with NSAIDs, including mefenamic acid, because NSAID administration may result in increased plasma levels of methotrexate, especially in patients receiving high doses of methotrexate.

Tacrolimus: Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.

OVERDOSAGE
Seizures, acute renal failure, coma, confusional state, vertigo, and hallucination have been reported with mefenamic acid overdoses. Overdose has led to fatalities.

Patients should be managed by symptomatic and supportive care following an NSAID overdose. There are no specific antidotes. Following acute overdosage, emesis, and/or gastric lavage, and/or activated charcoal may be considered dependent upon amount ingested and time since ingestion. Vital functions should be monitored and supported. Hemodialysis is of little value since mefenamic acid and its metabolites are firmly bound to plasma proteins.

LIST OF EXCIPIENT
Corn starch pregelatinized, Methyl cellulose, Sodium lauryl sulphate, Microcristalline cellulose, Corn starch, Cab-O-Sil-M-5-NF colloid, Purified water, HPMC, PEG 8000, Polysorbate 80, Saccharine sodium, Vanilin, Opaspray yellow K-I-F-6105, Wax candelilla.

STORAGE
Store below 30°C, protect from light.

SUPPLY
PONSTAN FCT 500 mg, box of 10 blisters @ 10 tablets; Reg. No.: DKL8519807117A1

HARUS DENGAN RESEP DOKTER

Manufactured by:
PT. Pfizer Indonesia
Jakarta, Indonesia

Brosur kemasan: Informasi bagi pengguna

PONSTAN 500 mg tablet salut selaput

Asam mefenamat

Bacalah brosur ini dengan cermat sebelum Anda menggunakan obat ini karena mengandung informasi yang penting untuk Anda.
- Simpan brosur ini. Anda mungkin perlu membacanya kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, apoteker, atau perawat Anda.
- Obat ini telah diresepkan hanya untuk Anda. Jangan berikan kepada orang lain. Obat ini dapat membahayakan mereka, sekalipun tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda mengalami efek samping apa pun, konsultasikan dengan dokter, apoteker, atau perawat Anda. Ini termasuk segala bentuk efek samping yang tidak tercantum di dalam brosur ini. Lihat bagian 8.

Isi brosur ini:

1. Nama produk
PONSTAN

2. Deskripsi produk
PONSTAN adalah tablet salut selaput. Tablet berbentuk elips, halus, tablet salut selaput berwarna kuning dengan logo P-D timbul di satu sisi dan garis dua di sisi lain.

3. Apa kandungan obat ini?
Dosis tunggal mengandung 500 mg asam mefenamat

4. Kekuatan obat
500 mg

5. Apa kegunaan obat ini?
PONSTAN diindikasikan untuk meredakan nyeri ringan hingga sedang pada:
- Artritis reumatoid
- Osteoartritis
- Cedera otot dan sakit gigi

- Sakit kepala
- Nyeri setelah pembedahan, melahirkan
- Dismenore primer
- Sindrom pramenstruasi

6. Berapa banyak dan seberapa sering Anda seharusnya menggunakan obat ini?

Nyeri ringan hingga sedang pada orang dewasa dan remaja berusia di atas 14 tahun: 500 mg tiga kali sehari.

Dismenore: 500 mg tiga kali sehari, diberikan sejak munculnya nyeri menstruasi dan diteruskan selama gejala berlanjut menurut pertimbangan dokter.

Sindrom pramenstruasi: 500 mg tiga kali sehari, dimulai sejak munculnya gejala dan berlanjut hingga perkiraan berhentinya gejala menurut pertimbangan dokter.

Penggunaan pada orang lanjut usia: Gangguan fungsi ginjal, kadang-kadang mengarah ke gagal ginjal akut, pernah dilaporkan. Orang lanjut usia dan pasien yang lemah tampaknya memiliki toleransi terhadap ulserasi atau perdarahan yang tidak sebaik sebagian individu lainnya; sebagian besar laporan spontan untuk kejadian saluran pencernaan yang fatal dialami oleh populasi pasien ini.

7. Kapan seharusnya Anda tidak menggunakan obat ini?

PONSTAN tidak diindikasikan untuk pasien yang mengalami kondisi berikut ini:

- Jika Anda alergi terhadap PONSTAN atau bahan lain yang terkandung dalam obat ini.
- Jika Anda pernah mengalami sesak nafas, rinitis alergi, dan biduran saat diterapi dengan asam asetil salisilat dan obat-obatan anti-inflamasi nonsteroid (OAINS) lainnya.
- Jika anda memiliki ulkus aktif atau peradangan kronis pada saluran pencernaan atas atau bawah.
- Jika Anda sudah memiliki penyakit ginjal.
- Jika Anda mengalami gagal hati berat.
- Jika Anda mengalami gagal jantung berat.
- Untuk meredakan nyeri setelah bedah bypass koroner pada jantung.

Kontraindikasi Tambahan untuk Penggunaan Spesifik
Kehamilan

Karena tidak ada penelitian yang memadai dan terkontrol dengan baik pada perempuan hamil, PONSTAN hanya boleh diberikan jika potensi manfaat bagi ibu hamil melebihi kemungkinan risikonya bagi janin. Dikarenakan efek obat dari golongan ini (yaitu penghambat sintesis prostaglandin) pada sistem kardiovaskular janin (misalnya penutupan dini duktus arteriosus), penggunaan asam mefenamat pada ibu hamil tidak dianjurkan dan harus dihindari selama kehamilan trimester ketiga. Perempuan yang menjalani terapi dengan PONSTAN harus berkonsultasi dengan dokter jika memutuskan untuk hamil.

Penghambatan sintesis prostaglandin dapat berdampak merugikan terhadap kehamilan. Data dari penelitian epidemiologis menunjukkan adanya peningkatan risiko aborsi spontan setelah penggunaan penghambat sintesis prostaglandin pada tahap awal kehamilan.

Jika digunakan selama kehamilan trimester kedua dan ketiga, OAINS dapat menyebabkan disfungsi ginjal pada janin sehingga mengakibatkan penurunan volume cairan amnion atau oligohidramnion dalam kasus yang berat. Efek semacam ini dapat terjadi tidak lama setelah pengobatan dimulai dan biasanya dapat dipulihkan setelah penghentian. Volume cairan amnion pada ibu hamil yang meminum asam mefenamat harus dipantau dengan saksama.

Menyusui
Sejumlah kecil asam mefenamat mungkin akan terkandung dalam ASI dan diteruskan kepada bayi. Oleh karena itu, ibu menyusui harus berkonsultasi dengan dokter apakah mereka boleh meminum PONSTAN selama menyusui.

Mengemudi dan mengoperasikan mesin
Dikarenakan kemungkinan efek samping seperti pening, mengantuk, kelelahan, dan gangguan penglihatan, maka PONSTAN dapat memengaruhi kemampuan Anda dalam bereaksi, menggunakan perkakas atau mesin, dan mengemudi.

8. Efek yang tidak diharapkan
Seperti halnya obat-obatan lainnya, PONSTAN dapat menimbulkan efek samping, kendati tidak semua orang mengalaminya. Jika efek samping bertambah parah, atau jika Anda mengalami efek samping yang tidak tercantum dalam brosur ini, harap konsultasikan dengan dokter, apoteker, atau perawat.

Gangguan sistem darah dan limfatik: Agranulositosis, anemia aplastik, anemia hemolitik autoimun*, hipoplasia sumsum tulang, penurunan hematokrit, eosinofilia, penurunan jumlah sel darah putih penurunan jumlah semua sel darah, dan trombositopenia purpura, inhibisi agregasi trombosit.

Gangguan sistem imun: Anafilaksis.

Gangguan metabolisme dan nutrisi: Intoleransi glukosa pada pasien diabetes, penurunan konsentrasi natrium dalam darah, retensi cairan.

Gangguan psikiatrik: Kegelisahan.

Gangguan sistem saraf: Meningitis aseptik, penglihatan kabur, kejang, pening, mengantuk, sakit kepala, dan insomnia.

Gangguan mata: Iritasi mata, hilangnya penglihatan warna reversibel.

Gangguan telinga dan labirin: Nyeri pada telinga.

Gangguan jantung: Peningkatan detak jantung.

Gangguan vaskular: Hipotensi, hipertensi.

Gangguan pernapasan, toraks, dan mediastinal: Asma, sesak.

Gangguan saluran pencernaan: peradangan saluran pencernaan, perdarahan saluran pencernaan, tukak saluran pencernaan, perforasi saluran pencernaan.

Efek samping yang paling sering dilaporkan dalam kaitannya dengan asam mefenamat adalah yang melibatkan saluran pencernaan. Diare tampaknya menjadi efek samping paling umum dan biasanya berkaitan dengan dosis. Efek samping ini umumnya akan mereda jika dosis diturunkan, dan segera berakhir jika terapi dihentikan. Beberapa pasien mungkin tidak dapat melanjutkan terapi.

Berikut ini adalah efek samping saluran pencernaan yang paling umum: nyeri abdomen, diare, dan mual dengan atau tanpa muntah.

Efek samping saluran pencernaan/hepatobilier yang tidak terlalu sering dilaporkan di antaranya: Anoreksia, kolestasis jaundice, kolitis, sembelit, enterokolitis, kembung, tukak lambung dengan dan

tanpa perdarahan, toksisitas hati ringan, hepatitis, sindrom hepatoadrenal, pirosis, radang pankreas, dan steatore.

Gangguan kulit dan jaringan subkutan: Angioedema, edema laring, eritema multiformis, edema wajah, sindrom Lyell (nekrolisis epidermal toksik), berkeringat, pruritus, ruam, sindrom Stevens-Johnson, kaligata/biduran, dan dermatitis eksfoliatif.

Gangguan ginjal dan perkemihan: nyeri berkemih, darah dalam urin, gagal ginjal termasuk nekrosis papiler, dan nefritis tubulointerstisial, glomerulonefritis, sindrom nefrotik.

Gangguan umum dan kondisi di lokasi pemberian: Edema

Pemeriksaan: Urine urobilinogen (positif palsu), tes fungsi hati abnormal

Pasien pediatrik
Gangguan umum dan kondisi di lokasi pemberian: Hipotermia.

*Laporan dikaitkan dengan terapi asam mefenamat ≥ 12 bulan dan anemia akan mereda jika terapi dihentikan.

9. Apa saja obat atau makanan lain yang harus dihindari selama menggunakan obat ini?
Beri tahu dokter, apoteker, atau perawat jika Anda sedang meminum atau baru-baru ini meminum obat lain, termasuk obat yang diperoleh tanpa peresepan. Terdapat beberapa obat yang mungkin akan berinteraksi dengan PONSTAN.

Bentuk sediaan oral asam mefenamat dapat diminum setelah makan apabila terjadi gangguan gastrointestinal.

10. Apa yang harus dilakukan jika ada dosis terlewat?
Beri tahu dokter, apoteker, atau tenaga kesehatan Anda untuk mengetahui kapan Anda harus meminum tablet PONSTAN berikutnya.

11. Bagaimana cara menyimpan obat ini?
- Jauhkan dari jangkauan dan penglihatan anak-anak.
- Simpan pada suhu di bawah 30°C, jauhkan dari cahaya.

12. Tanda dan gejala kelebihan dosis
Kejang, gagal ginjal akut, koma, linglung, vertigo, dan halusinasi telah dilaporkan saat terjadi overdosis asam mefenamat. Overdosis dapat mengakibatkan kematian.

13. Apa yang harus dilakukan jika Anda menggunakan dosis melebihi anjuran?
Beri tahu dokter, apoteker, atau perawat jika Anda mengalami kelebihan dosis.

Pasien harus ditangani dengan perawatan simtomatik dan suportif jika terjadi kelebihan dosis OAINS. Tidak ada antidot spesifik. Setelah kejadian overdosis yang tidak disengaja, emesis dan/atau bilas lambung, dan/atau karbon aktif dapat dipertimbangkan bergantung pada jumlah yang tertelan dan durasi waktu sejak obat tertelan. Fungsi vital harus dipantau dan ditunjang. Hemodialisis tidak terlalu berpengaruh karena asam mefenamat dan metabolitnya terikat kuat pada protein plasma.

14. Apa saja yang perlu diperhatikan saat menggunakan obat ini?
Sebelum meminum obat ini, beritahu dokter Anda jika Anda:
- Meminum obat anti inflamasi non steroid (OAINS) lain (misalnya parasetamol, ibuprofen, diklofenak, dan sebagainya).

- Memiliki gangguan lambung atau pencernaan atau jika Anda pernah mengalami sakit perut setelah mengonsumsi OAINS. Pendarahan di saluran pencernaan dapat terjadi pada pasien yang mengonsumsi PONSTAN.
- Pernah mengalami gangguan pendarahan atau jika Anda akan menjalani operasi besar, PONSTAN dapat mempengaruhi darah Anda. Itu bisa membuat Anda lebih berdarah dan lebih lama dari biasanya
- Lanjut usia
- Memiliki tekanan darah tinggi.
- Memiliki masalah jantung, stroke sebelumnya atau berpikir bahwa Anda mungkin berisiko terhadap kondisi ini (misalnya jika Anda memiliki tekanan darah tinggi, diabetes atau kolesterol tinggi atau perokok).
- Mengkonsumsi obat-obatan yang mengencerkan darah (misalnya Warfarin) - Menderita asma, atau riwayat asma, karena obat ini dapat menyebabkan kesulitan bernapas.
- Jika Anda menggunakan metotreksat maka asam mefenamat dapat meningkatkan kadar metotreksat dalam plasma.
- Jika Anda diketahui atau diduga memiliki metabolisme CYP2C9 yang lemah.
- Jika Anda memiliki retensi cairan atau gagal jantung.
- Jika Anda meminum alkohol.
- Jika Anda meminum kortikosteroid, obat antiplatelet (seperti aspirin), antikoagulan, atau penghambat penyerapan kembali serotonin selektif oral.
- Jika Anda meminum penghambat ACE atau AIIA, dan/atau diuretik.
- Status kesehatan secara umum tergolong buruk.

15. Kapan sebaiknya Anda berkonsultasi dengan dokter?
Jika Anda memiliki pertanyaan lebih lanjut atau Anda mengalami situasi yang sama seperti yang tercantum dalam brosur ini, konsultasikan dengan dokter, apoteker, atau perawat Anda.

16. Daftar Zat Tambahan
Corn starch pregelatinized, Methyl cellulose, Sodium lauryl sulphate, Microcristalline cellulose, Corn starch, Cab-O-Sil-M-5-NF colloid, Purified water, HPMC, PEG 8000, Polysorbate 80, Saccharine sodium, Vanilin, Opaspray yellow K-I-F-6105, Wax candelilla.

17. Nama produsen/importir/Pemegang Hak Pemasaran
Diproduksi oleh:
PT. Pfizer Indonesia
Jakarta, Indonesia

HARUS DENGAN RESEP DOKTER

PONSTAN FCT 500 mg; Dus, 10 blister @ 10 tablet; Reg. No.: DKL8519807117A1

18. Tanggal revisi
01/2024