HOSTAN

VIHOS23-0 (MY)

Description

HOSTAN 250 Capsule:
Green opaque and grey opaque capsule with “HT 250” printed on one end and “HD” on the other end of the capsule

HOSTAN 250 Tablet:
Round, yellow uncoated tablet, shallow convex faces and scored on one face.

Composition

Hostan Capsule : Mefenamic acid 250mg per capsule
Hostan Tablet : Mefenamic acid 250mg per tablet

Pharmacodynamics

Mefenamic acid blocks pain impulse generation via a peripheral action which may involve inhibition of the synthesis of prostaglandins, and possibly inhibition of the synthesis or actions of other substances which sensitize pain receptors to mechanical or chemical stimulation.

Mefenamic acid also competitively inhibits the actions of prostaglandins.

Mefenamic acid exerts an anti-inflammatory effect by acting peripherally in inflamed tissue. It inhibits the synthesis of prostaglandins and the synthesis and / or actions of other local mediators of the inflammatory response. Inhibition of leukocyte migration, inhibition of the release and / or actions of lysosomal enzymes, and actions on other cellular and immunological processes in messenchymal and connective tissue may be involved.

Being a prostaglandin synthesis inhibitor as well as a inhibitor of the actions of prostaglandins, mefenamic acid is effective in relieving dysmenorrhoea. The endometrium is a major site of prostaglandin synthesis and prostaglandins can cause excessive myometrial contractility, leading to uterine ischaemia and pain. The actions of prostaglandins on the myometrium is reduced by mefenamic acid.

Pharmacokinetics

Absorption
Mefenamic acid is well absorbed from the gastrointestinal tract after an oral dose. Peak concentrations in the circulation occur about 2 hours after ingestion.

Blood Concentration
When therapy is started with an initial dose of 500mg, and continued with 250mg thrice daily, plasma concentrations of 0.3 to 3.6 microgram/ml are attained 2 hours after the last dose.Peak plasma concentrations are attained in 2 to 4 hours after a single dose.

Half-life
The half-life in plasma is 3 to 4 hours.

Protein Binding
Mefenamic acid is extensively bound to plasma proteins.

Distribution
Mefenamic acid does not appear to accumulate in the body but small amounts are secreted in breast milk.

Metabolism
The drug is metabolized in the liver by hydroxylation of the 3-methyl group. This is followed by oxidation to produce the 3-carboxy metabolite, and conjugation.

Excretion
Approximately 50% of a dose may be recovered in the urine within 48 hours, mainly as conjugated metabolites. 20% of the drug is recovered in the faeces, mainly as the unconjugated 3-carboxyl metabolite.

Clinical Significance of data
There is the possibility of the displacement of other drugs, from non-specific binding sites on plasma albumin by mefenamic acid, as it binds strongly to plasma proteins.

Indications

For the relief of mild to moderate pain including headache, dental pain, postoperative and postpartum pain, and dysmenorrhoea. It is used in rheumatic disorders such as osteoarthritis and rheumatoid arthritis.

Contraindications

Not recommended for patients with intestinal ulceration or inflammatory bowel disease, and in patients hypersensitive to mefenamic acid as well as in patients with a potential risk for cross-sensitivity to aspirin and other NSAIDs.

Warnings and Precautions

RISK OF GI ULCERATION, BLEEDING AND PERFORATION WITH NSAID

Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor upper GI problems (e.g. dyspepsia) are common, usually developing early in therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms.
Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious adverse events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking, corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

- It should be used with caution in patients with impaired renal or liver function.
- It may enhance the effects of the coumarin anti-coagulants.
- It should be used with caution in elderly patients suffering from dehydration and renal disease.

- Therapy should be discontinued if diarrhoea or skin rash occur.
- Bronchospasm may be precipitated in patients suffering from, or have a previous history of, bronchial asthma or allergic disease.
- This drug is preferably administered after meals or with food or antacids to reduce gastrointestinal irritation.
- Therapy with this drug should not be given for more than 7 days at a time.
- Mefenamic acid may cause drowsiness in some patients. Avoid alcoholic beverages as this may increase the effects as well as causing stomach upsets.

Pregnancy and Lactation

Safety for use has not been established in children under 14 years of age, in pregnancy and lactation.

Interaction with Other Medicaments and Other Forms of Interaction

- Co-administration of alcohol or other anti-inflammatory medications may increase the risk of gastrointestinal side effects and/or ulceration.
- Effects of coumarin or indanedione derivative anticoagulants may be potentiated when used concurrently with mefenamic acid.
- Concurrent use with aspirin or other salicylates may increase the incidence of gastrointestinal side effects without providing additional symptomatic relief

Main Side/ Adverse Effects

The most common side-effects are gastro-intestinal disturbances. Others include peptic ulceration, gastro-intestinal bleeding, headache, drowsiness, dizziness, nervousness, visual disturbances, hypersensitivity reactions including skin rashes and urticaria, thrombocytopenia and haemolytic anaemia. Severe cutaneous reactions have also been reported.

Effects 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

Overdose

Symptoms:
Nausea, vomiting, bloody diarrhoea, drowsiness, dizziness, headache, hyper-twitching, convulsions, coma, skin-rash, haemolytic anaemia.

Treatment:
Treat overdosage by emesis or gastric lavage; administer activated charcoal to reduce the absorption and control convulsions, if any, with 5 - 10 mg IV diazepam.

Dosage and Administration

Adults: Oral, 500 mg initially, followed by 250 mg every six hours, as needed.

Note: The information given here is limited. For further information, consult your doctor or pharmacist.

Storage : (Blister pack) Store below 30˚C.
Protect from moisture.
(Bottle) Store below 25°C.
Protect from moisture.

Presentation/packing : (Capsule) Blister pack of 100's, 1000's; Bottle of 1000's
(Tablet) Blister pack of 100's; Bottle of 1000's
(Not all presentations may be available locally.)

Product Registration Holder: Hovid Bhd.,
121, Jalan Tunku Abdul Rahman, 30010 Ipoh, Malaysia

Manufactured by: Hovid Bhd.,
Lot 56442, 7 ½ Miles, Jalan Ipoh / Chemor, 31200 Chemor, Malaysia.

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