Pentasa® Xtend 2gm

FERRING

Composition

Active substance: Mesalazine (5-aminosalicylic acid)

Galenic form and quantity of active substance per unit

Slow release granules, sachets of 2 g

Therapeutic indications/possible applications

Slow release granules:

Acute treatment of ulcerative colitis Proctosigmoiditis, Proctitis & crohn's disease.

Posology/method of administration

Ulcerative colitis, Proctosigmoiditis & Proctitis

Active disease:

Individual dosage, up to 4 g mesalazine daily divided into 2-4 doses

Maintenance treatment:

Individual dosage. Recommended dosage, 2 g mesalazine once daily.

Crohn's disease:

Active disease and maintenance treatment.

Adults:Individual dosage,up to 4g mesalazine daily in divided dose.

Childern & adolescents:

No studies on the efficacy and safety in paediatric have been performed. The adult dose can be administered to adolescents. There is limited experience in the acute treatment of childern from 2-12 years of age at doses of 30 mg/kg/day. A maximum daily dose of 2g should not be exceeded.

As with adults, half of this dose should be used for maintenance prophylaxis.

Instructions for use

Pentasa slow release granules: empty contents of sachet into mouth and wash down with fluid. Do not chew.

Contraindications

Treatment with Pentasa should be avoided in the case of known salicylate allergy and severe functional disturbance of the liver or kidneys. Pentasa should not be used in patients with gastric or duodenal ulcers or pathologically increased bleeding tendency.

PENTASA Should not be used in children under 2 years.

Special warnings and precautions

A reduced dose is advised in the case of functional disturbances of the liver or kidneys.

Interactions

The blood sugar-reducing effect of sulphonylurea and the gastrointestinal bleeding triggered by coumarin can be increased. Methotrexate toxicity can be increased. The uricosuric effect of probenecid and sulphinpyrazone can be reduced, as can the diuretic effects of furosemide and spironolactone. The antituberculous effect of rifampicin can be weakened. Mesalazine may possibly increase the undesirable effects of glucocorticoids on the stomach.

Mesalazine may reduce digoxin absorption.

A potential risk of myelosuppression; particularly leucopenia when aminosalicylates are coadministered with azathioprine or 6- mercaptopurine.A potential risk of renal failure when aminosalicylates are coadministered with other nephrotoxic agents such as NSAIDs and azathioprine.

Pregnancy/lactation

PENTASA should be used with caution during pregnancy and lactation and only if the potential benefits outweigh the possible hazards in the opinion of the physician.

Mesalazine is known to cross the placental barrier and its concentration in umbilical cord plasma is one tenth of the concentration in maternal plasma. The metabolite acetyl-mesalazine is found in the same concentration in umbilical cord and maternal plasma. From several observational studies no teratogenic effects are reported and there is no evidence of significant risk of use in humans. In animal studies no teratogenic or mutagenic effects have been observed.

Blood disorders(pancytopenia,leucopenia,thrombocytopenia, anaemia) have been reported in new-borns of mothers being treated with PENTASA.

Mesalazine is excreted in breast milk. The Mesalazine concentration in breast milk is lower than in maternal blood, whereas the metabolite - acetyl-mesalazine - appears in similar or increased concentrations. There is limited experience of the use of oral mesalazine in lactating women. No controlled studies with PENTASA during breast-feeding have been carried out. Hypersensitivity reactions like diarrhoea in the infant can not be excluded.

Effect on the ability to drive and operate machinery

Due to the possible side effects of nausea and dizziness, Pentasa can impair the ability to drive and operate machinery.

Undesirable effects

Nervous system

Occasional: headache, nausea, dizziness

Immune system

Rare: hypersensitivity reaction irrespective of dose with allergic exanthema, drug fever, bronchospasm and similar symptoms to lupus erythmatodes. Patients with a salicylate allergy react to mesalazine accordingly.

Gastrointestinal system

Rare: vomiting, pancreatitis

Liver

Rare: functional disturbance of the liver with raised enzyme and transaminase levels

Kidneys

Rare: interstitial nephritis

Blood and lymphatic system

Very rare: thrombocytopenia, neutropenia, raised methaemoglobin levels, aplastic anaemia, pancytopenia

Heart : Very rare : myocarditis, pericarditis

Lungs

Very rare: alveolitis

After intake of a high dosage of mesalazine (4 g/day) in rare instances alopecia has occurred, but this is reversible following reduction of the dose or discontinuation of the drug.

Overdose

Due to the galenic properties of Pentasa and the substance-specific pharmacokinetic properties of mesalazine, only small quantities of the active substance are available for a systemic effect. Therefore signs of intoxication should not necessarily be expected, even if high doses are taken. Theoretically there should be symptoms similar to known signs of salicylate poisoning: mixed acidosis/alkalosis, hyperventilation, pulmonary oedema, dehydration due to sweating and vomiting, hypoglycaemia.

Treatment: for mixed acidosis/alkalosis: restoration of acid/base balance according to the situation and electrolyte substitution. For dehydration due to sweating and vomiting: give fluids. For hypoglycaemia: give glucose.

Shelf life:

The drug must not be used after the date "Exp" shown on the packaging.

Special storage instructions:

Store at room temperature (below 25°C) in the original packaging away from light. Keep out of reach of children.

List of excipients: Povidone, Ethylcellulose

Manufacturer & MAH:

Ferring S.A, St. Prex. Switzerland.

Date of revision of text:

April 2005.

THIS IS A MEDICINE

- A MEDICINE IS A PRODUCT WHICH AFFECTS YOUR HEALTH.AND ITS CONSUMPTION CONTRARY TO INSTRUCTIONS IS DANGEROUS FOR YOU.
- STRICTLY FOLLOW THE DOCTOR'S PRESCRIPTION, THE METHOD OF USE AND THE INSTRUCTIONS OF THE PHARMASIST WHO SOLD THE MEDICINE.
- THE DOCTORS AND THE PHARMACIST ARE EXPERTS IN MEDICINE,ITS BENEFITS AND RISKS.
- DO NOT BY YOURSELF INTERRUPT THE PERIOD OR TREATMENT PRESCRIBED FOR YOU.
- DO NOT REPEAT THE SAME PRESCRIPTION WITHOUT CONSULTING YOUR DOCTOR.
- KEEP THE MEDICINE OUT OF REACH OF CHILDREN.

Council of Arab Health Ministers
Union of Arab Pharmacists

2009051976