



سالزینا
(میسالازین) ۴۰۰ ملی گرام ٹیبلٹس بی۔ پی۔

QUALITATIVE AND QUANTITATIVE COMPOSITION

Salzina® 400mg Tablets

Each prolonged-release tablet contains:

Mesalazine B.P.400mg

DESCRIPTION

Mesalazine (also referred to as 5-aminosalicylic acid or 5-ASA) has the chemical name 5-amino-2hydroxybenzoic acid.

CLINICAL PHARMACOLOGY

Pharmacodynamic properties:

Mesalazine is one of the two components of sulphasalazine, the other being sulphapyridine. It is the latter which is responsible for the majority of the side effects associated with sulphasalazine therapy whilst mesalazine is known to be the active moiety in the treatment of ulcerative colitis.

Mechanism of action: Data not available

Pharmacokinetics: Mesalazine Tablets contain 400 mg of available mesalazine. This is released in the terminal ileum and large bowel by the effect of pH. Above pH 7 the coat disintegrates and releases the active constituent.

THERAPEUTIC INDICATIONS

Ulcerative Colitis:

For the treatment of mild to moderate acute exacerbations. For the maintenance of remission.

Crohn's ileo-colitis

For the maintenance of remission.

CONTRAINDICATIONS

A history of sensitivity to salicylates or renal sensitivity to sulphasalazine. Confirmed severe renal impairment (GFR less than 20 ml/min). Children under 2 years of age.

INTERACTIONS

Mesalazine Tablets should not be given with lactulose or similar preparations, which lower stool pH and may prevent release of mesalazine. Concurrent use of other known nephrotoxic agents, such as NSAIDs and azathioprine, may increase the risk of renal reactions.

USE IN SPECIFIC POPULATION

Pregnancy & Breast feeding:

No information is available with regard to teratogenicity; however, negligible quantities of mesalazine are transferred across the placenta and are excreted in breast milk following sulphasalazine therapy. Use of 'Mesalazine' during pregnancy should be with caution, and only if the potential benefits are greater than the possible hazards. 'Mesalazine' should, unless essential, be avoided by nursing mothers.

Fertility: No data available.

WARNINGS AND PRECAUTIONS

Use in the elderly should be cautious and subject to patients having normal

renal function.

Renal disorder: Mesalazine is excreted rapidly by the kidney, mainly as its metabolite, N-acetyl-5-aminosalicylic acid. In rats, large doses of mesalazine injected intravenously produce tubular and glomerular toxicity. Mesalazine should be used with extreme caution in patients with confirmed mild to moderate renal impairment. Patients on mesalazine should have renal function monitored, (with serum creatinine levels measured) prior to treatment start. Renal function should then be monitored periodically during treatment, for example every 3 months for the first year, then 6 monthly for the next 4 years and annually thereafter, based on individual patient history. Physicians should take into account risk factors such as prior and concomitant medications, duration and severity of disease and concurrent illnesses. Treatment with mesalazine should be discontinued if renal function deteriorates. If dehydration develops, normal electrolyte and fluid balance should be restored as soon as possible. Serious blood dyscrasias have been reported very rarely with mesalazine. Haematological investigations should be performed if the patient develops unexplained bleeding, bruising, purpura, anaemia, fever or sore throat. Treatment should be stopped if there is suspicion or evidence of blood dyscrasia.

ADVERSE REACTIONS

The side effects are predominantly gastrointestinal, including nausea, diarrhoea and abdominal pain. Headache has also been reported. There have been rare reports of leucopenia, neutropenia, agranulocytosis, aplastic anaemia and thrombocytopenia, alopecia, peripheral neuropathy, pancreatitis, abnormalities of hepatic function and hepatitis, myocarditis and pericarditis, allergic and fibrotic lung reactions, lupus erythematosus-like reactions and rash (including urticaria), drug fever, interstitial nephritis and nephrotic syndrome with oral mesalazine treatment, usually reversible on withdrawal. Renal failure has been reported. Mesalazine induced nephrotoxicity should be suspected in patients developing renal dysfunction during treatment. Mesalazine may very rarely be associated with an exacerbation of the symptoms of colitis, Stevens Johnson syndrome and erythema multiforme. Other side effects observed with sulphasalazine such as depression of sperm count and function, have not been reported with 'Mesalazine'.

DOSAGE AND ADMINISTRATION

ADULTS:

Oral:

Acute disease: Six tablets a day in divided doses, with concomitant corticosteroid therapy where clinically indicated.

Child 12–17 years: 800 mg 3 times a day

Maintenance therapy: Three to six tablets once daily or in divided doses. Maintenance therapy for Child 12–17 years: 400–800 mg 2–3 times a day.

ELDERLY: The normal adult dosage may be used unless renal function is impaired.

Method of administration: Oral use. Swallow whole with water. Do not break, crush or chew the tablets before swallowing. **Overdose:** Following tablet ingestion, gastric lavage and intravenous transfusion of electrolytes to promote diuresis. There is no specific antidote.

DOSAGE: As directed by the physician.

INSTRUCTIONS: Store below 25°C. Protect from sunlight & moisture. Keep all medicines out of the reach of children.

PRESENTATION

Salzina® 400mg prolong-release tablets B.P. available in 5x10's Alu-Alu blister pack.

علامات / طریقہ استعمال :- یہ دوا السریٹو کولائٹس اور کروہن آئیلیو کولائٹس کی بیماری کے لئے تجویز کردہ ہے۔

مضر اثرات :- سردرد، متلی، پیٹ میں درد، لیکوپیڈیا، نیوٹروفیلیا، ایگریٹو سٹیٹوس، پریفیبرل نیوروپیتھی، ایلوپسیا، ہپاٹائٹس۔

احتیاطی تدابیر :- بزرگ افراد احتیاط سے استعمال کریں۔
گردوں کے مریضوں میں یہ دوا انتہائی احتیاط کے ساتھ استعمال کریں۔
مضر اثرات آنے کی صورت میں استعمال روک دیں۔
حاملہ خواتین یہ دوا صرف ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

خوراک :- معالج کے مشورے سے استعمال کریں۔

ہدایات :- ۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
سورج کی روشنی اور نمی سے محفوظ رکھیں۔ تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔
صرف مستند معالج کے نسخے پر فروخت کریں۔

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