PACKAGE LEAFLET

SULFAGUANIDIN

ATC code: A07AB03

PHARMACOTHERAPEUTIC GROUP
Intestinal anti-infectious agents. Sulfonamides.

COMPOSITION
Sulfaguanidine 500 mg in one tablet.

ACTION
Sulfonamide antibacterial preparation for treatment of intestinal infections, caused by sulfaguanidine-sensitive microorganisms. It competitively inhibits para-aminobenzoic acid and prevents folic acid formation in the bacterial cell. It exhibits bacteriostatic activity against a number of pathogens causing intestinal infections - Escherichia coli, Shigella, Salmonella.

It is slowly and poorly absorbed from the gastrointestinal tract where it creates high concentrations and exerts local antimicrobial action. It crosses poorly the placental-fetal barrier and is excreted in small amounts in breast milk. It is eliminated in small amounts through the kidneys.

INDICATIONS
Intestinal infections: bacterial dysentery, colitis and enterocolitis with diarrhea, gastroenteritis, summer diarrhea of bacterial origin; carriers of dysentery and typhus bacteria; for preoperative bowel sterilization and for prevention of postoperative bowel complications.
CONTRAINDICATIONS

Allergy to sulphonamides; concurrent administration with derivatives of paraaminobenzoic acid and local anesthetics which have similar structure (anesthesine, procaine, etc.); ulcerative colitis; severe kidney and liver disorders; heart failure; leucopenia; glucose-6-phosphate dehydrogenase (G6PD) deficiency.

ADVERSE REACTIONS/SIDE EFFECTS

Gastrointestinal disturbances are most common: loss of appetite, nausea, dysbosis (hypovitaminosis B and K) during prolonged use, candidosis. Because of the poor absorption of sulfaguanidine, other adverse reactions are less common: allergic rash and eruptions, photosensitization; hematologic disturbances like leucopenia, methemoglobinemia, hemolytic anemia (in individuals with glucose-6-phosphate dehydrogenase deficiency), hyperbilirubinemia in neonates and premature infants; nephrotoxic effects - oliguria, albuminuria, urinary tract (kidney pelvis, ureters, urinary bladder) obstruction, deposition of acetylated sulfaguanidine; endotoxin shock; tendency to bleeding (vitamin K₃).

DRUG AND OTHER INTERACTIONS

The antimicrobial effect of sulfonamides is decreased by concurrent administration of local anesthetics, esters of para-aminobenzoic acid (anesthesine, procaine, gericaine). Administration of hexamethylenetetramine (methenamine) before, during, and after treatment with sulfaguanidine and other sulfonamides raises a risk of kidney stone formation. Sulfaguanidin may be used concomitantly with chloramphenicol, tetracyclines or other antibiotics, or with sulfonamides with better absorption.
PRECAUTIONS AND WARNINGS

To avoid adverse effects from the urinary tract (precipitation of acetylated sulfaguanidine), increased urinary output should be provided by taking large amounts of fluids - 2 - 3 liters daily.

Vitamin B complex group and vitamin K should be taken during prolonged use of sulfaguanidine. If necessary, it may be combined with antibiotics and sulfonamides with better absorption from the gastrointestinal tract.

PREGNANCY AND BREAST FEEDING

This preparation should not be administered during the first trimester of pregnancy, one week before the expected term of delivery, during breast-feeding, and to neonates and infants until 3-4 months of age.

EFFECT ON ACTIVE ATTENTION, DRIVING AND OPERATION OF MACHINERY

There are no reports of adverse effects on active attention, reflexes, and motor activity.

MODE OF ADMINISTRATION AND DOSAGE

For treatment of bacterial dysentery in adults, 1-2 g for a course of 5-7 days, on day 1 every 4 h, on day 2 every 6 h, from day 3 onward every 6-8 h. Maximal single dose 2 g. Total course dose 40-45 g.

For subacute and chronic intestinal infections, 500 mg to 1 g 4-5 times daily. It may be administered as enema, 7 g in 20 ml water, once daily for the course of 6-7 days.

For preoperative bowel sterilization, the recommended dosage schedule is 50 mg/kg every 8 h for 4-5 days before the operation.

For children, 200-300 mg/kg/24 h, in 6 divided doses every 4 h until body temperature falls down, and then reduction of daily dose to 50-100 mg/kg.
OVERDOSAGE

Because of the poor absorption of the preparation, the symptoms of overdosage are mainly from the gastrointestinal tract: nausea, vomiting, diarrhea. Other symptoms include allergic reactions, oliguria, albuminuria, anuria; leucopenia, hemolytic anemia, hyperbilirubinemia. Treatment - measures to remove the drug from the gastrointestinal tract (gastric lavage, activated charcoal). Forced diuresis in preserved kidney function. Symptomatic agents.

DOSAGE FORM AND PACKAGES

Tablets of 500 mg, 10 tablets in a unit package.

STORAGE

In a dry place, protected from light, at temperature 15-25°C.