

Sodipic

Sodium Picosulfate BP

COMPOSITION

Sodipic Tablet: Each film coated tablet contains Sodium Picosulfate BP 10 mg.

Sodipic Oral Solution: Each 5ml oral solution contains Sodium Picosulfate BP 5 mg.

PHARMACOLOGY

Sodium Picosulfate is a triaryl methane group derivative stimulant laxative. After oral administration it is activated by the colonic bacteria and acts locally in the colon. The active form then stimulates the nerve endings of the intestinal wall and results in colonic peristalsis with promotion of accumulation of water and electrolytes in the colonic lumen. This results in stimulation of defecation, reduction of transit time and softening of the stool. Stimulation of the rectum causes increased motility and a feeling of rectal fullness. The rectal effect may help to restore the "call to stool".

INDICATION & USES

Constipation of any etiology, relief from prolonged & recurrent constipation, bowel clearance before surgery, childbirth or radiological investigations.

DOSAGE & ADMINISTRATION

For oral administration. The following dosages are recommended to be taken at night to produce evacuation the following morning. It is recommended to start with the lowest dose. The dose may be adjusted up to the maximum recommended dose to produce regular stools. The maximum recommended daily dose should not be exceeded:

Age	Tablet dose/day	Oral Solution dose/day
Adult and children above 10 years	5 - 10 mg	5-10 ml (One to two teaspoonful per day)
Children aged 4-10 years	2.5 – 5 mg	2.5-5 ml (Half to one teaspoonful per day)
Children aged 1 month- 4 years	—	0.25 ml/kg body weight per day

CONTRAINDICATION

Ileus or intestinal obstruction, severe painful and/or feverish acute abdominal conditions (e.g. appendicitis) potentially associated with nausea and vomiting, acute inflammatory bowel diseases, severe dehydration, known hypersensitivity to Sodium Picosulfate or any other component of the product.

WARNING & PRECAUTION

Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalemia. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.

SIDE EFFECTS

Hypersensitivity, dizziness, syncope, vasovagal response, gastrointestinal disorders, diarrhea, abdominal pain and abdominal cramps, nausea, vomiting.

USE IN SPECIAL GROUP

Pregnancy & Lactation

There are no reports of undesirable or damaging effects during pregnancy or to the foetus attributable to the use of this product. Use of the drug should be avoided during first trimester. Clinical data show that neither the active moiety of Sodium Picosulfate (BHPPM or bis-(p hydroxyphenyl)-pyridyl-2-methane) nor its glucuronides are excreted into the milk of healthy lactating females.

Use in the elderly

The safety & efficacy of Sodium Picosulfate in elderly population have not been established. Caution should be exercised in the elderly as dehydration and electrolyte depletion may occur. Elderly patients must receive adequate fluids during administration.

Hepatic & Renal Impairment

Sodium Picosulfate should not be used in patients with clinically significant renal impairment. Patients with kidney disease or impaired kidney function should be monitored. No data available for hepatic impairment patients.

DRUG INTERACTIONS

The concomitant use of diuretics or Adreno-corticosteroids may increase the risk of electrolyte imbalance if excessive doses are taken. Concurrent administration of antibiotics may reduce the laxative action of this product.

OVERDOSE

Laxatives when taken in chronic over dosage may cause chronic diarrhea, abdominal pain, hypokalemia, secondary hyperaldosteronism and renal calculi. Renal tubular damage, metabolic alkalosis and muscle weakness secondary to hypokalemia have also been described in association with chronic laxative abuse.

STORAGE

- Store below 30° C. temperature & dry place, protected from light.
- Keep out of reach of children.

PACKAGING

Sodipic Tablet: Each box contains 30's Tablets in Alu-Alu blister pack.

Sodipic Oral solution: Each bottle contains 100 ml oral solution.