

Picorif[®]

Sodium Picosulfate

COMPOSITION:

Picorif[®] Tablet: Each film coated tablet contains Sodium Picosulfate BP 10 mg.

Picorif[®] Oral Solution: Each 5 ml of oral solution contains Sodium Picosulfate BP 5 mg.

PHARMACOLOGY:

Sodium Picosulfate is a triarylmethane 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:

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

DOSE & 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	Dose: Picorif 10 Tab	Dose: Picorif Oral Solution
Adults & children over 10 years of age	5 - 10 mg per day	5-10 ml or One to two teaspoonful per day.
Children 4 - 10 years	2.5 - 5 mg per day	2.5 - 5 ml or half to one teaspoonful per day
Children under 4 years of age		0.25 ml / kg body weight per day

CONTRA-INDICATION:

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 AND 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 PREGNANCY & LACTATION:

Pregnancy: 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.

Lactation: Clinical data show that neither the active moiety of sodium Picosulfate (BHPM or bis-(p hydroxyphenyl)-pyridyl-2-methane) nor its glucuronides are excreted into the milk of healthy lactating females.

USE IN CHILDREN & ADOLESCENTS:

No sufficient data available. According to dosage guideline may be administrate from one month of age or recommended by the consultation with physicians.

DRUG INTERACTION:

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 in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Picorif[®] Tablet: Each box contains 2 x 10's tablets in Alu-Alu blister pack.

Picorif[®] Oral Solution: Each bottle contains 100 ml oral solution and a 10 ml measuring cup



Manufactured by

Team Pharmaceuticals Ltd.

B 75-79, BSCIC, Rajshahi, Bangladesh

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