

Picosul[®]

Sodium Picosulfate BP

Description: Picosul[®] (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.

Mode of action: Sodium Picosulfate is activated by the colonic bacteria. 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".

Composition: Picosul[®] 10 Tablet: Each tablet contains Sodium Picosulfate BP 10 mg.

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

Indications: Picosul[®] (Sodium Picosulfate) tablet/oral solution is indicated for short term relief of prolonged and recurrent constipation and for the management of constipation of any etiology.

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	Picosul [®] 10 Tablet	Picosul [®] Oral Solution
Adults and children (over 10 years)	5-10 mg per day	5-10 ml or one to two teaspoonful per day
Children aged 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

Contraindications: 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.

Side effects: Hypersensitivity, Dizziness, Syncope, Vasovagal response, Gastrointestinal disorders, Diarrhea, Abdominal pain and abdominal cramps, Nausea, Vomiting.

Use in pregnancy & lactation: There are no adequate and well-controlled studies in pregnant women. Long experience has shown no evidence of undesirable or damaging effects during pregnancy. Clinical data shows that neither the active moiety of Sodium Picosulfate nor its glucuronides are excreted into the milk of healthy lactating females.

Precautions: Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalemia. It should not be taken by children under 10 years without medical advice. 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.

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.

Over dosage: 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: Keep out of reach of children. Store in a dry place, below 25° C temperature and protected from light.

Packaging:

Picosul[®] 10 Tablet: Each box contains 10X3 Tablets in Alu-Alu blister pack.

Picosul[®] 100 ml Oral Solution: Each bottle contains 100 ml oral solution.

Picosul[®] 50 ml Oral Solution: Each bottle contains 50 ml oral solution.