

# Sopilax™

Sodium Picosulfate BP

Tablet 10 mg  
Oral Solution 100 ml

## Composition

**Sopilax™** 10 Tablet: Each tablet contains Sodium Picosulfate BP 10 mg.

**Sopilax™** 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".

## Indications

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

## 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	Sopilax™ 10 Tablet	Sopilax™ Oral Solution
Adults and children over 10 years of age	5 -10 mg per day	5-10 ml or 1 to 2 teaspoonful per day
Children aged 4 - 10 years	2.5 - 5 mg per day	2.5-5 ml or ½ to 1 teaspoonful per day
Children from 1 month to 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.

## 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.

## Pregnancy

There are no reports of undesirable or damaging effects during pregnancy or to the fetus 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.

## 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.

## Overdoses

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 weakness secondary to hypokalemia have also been described in association with chronic laxative abuse.

## Storage Condition

Store below 30° C. Protected from light and moisture. Keep all medicines out of the reach of children.

## How Supplied

**Sopilax™** 10 Tablet: Box containing 20 Tablets in Alu-Alu blister.

**Sopilax™** Oral Solution: Bottle containing 100 ml Oral Solution.

Manufactured by



**SQUARE**  
PHARMACEUTICALS LTD.  
BANGLADESH