

Skilax®

(Sodium Picosulfate)



COMPOSITION

Skilax 5mg Tablet:

Each tablet contains: Sodium Picosulfate 5mg

Skilax Drops:

Each ml contains: Sodium Picosulfate 7.5mg

Each ml contains approximately 20 drops.

Each drop contains 0.375mg Sodium Picosulfate.

DESCRIPTION

The active ingredient in Skilax is Sodium Picosulfate which is a stool softening laxative taken orally.

MECHANISM OF ACTION

Sodium Picosulfate is a stimulant laxative, after metabolism in the colon, it stimulates the mucosa thereby increasing the motility of the large intestine.

PHARMACOKINETIC

Sodium picosulfate is metabolized by colonic bacteria to the active compound bis (p-hydroxyphenyl) pyridyl -2-methane. Only a small amount of sodium picosulfate is absorbed after an oral dose; this is subsequently excreted in the urine.

INDICATIONS

It is indicated in the following conditions;

- Constipation
- Evacuation of colon before investigation procedures or surgery

DOSAGE AND ADMINISTRATION

For oral administration.

Unless otherwise prescribed by the doctor, the following dosages are recommended:

Adults: For constipation, it is given as a single dose of 5 to 10 mg usually at bed time. For bowel evacuation a dose of sodium picosulfate 10mg with magnesium citrate is given in the morning and again in the afternoon of the day before examination.

Children over 10 years: A dose of 5 to 10mg

Children under 4 to 10 years: A dose of 2.5 to 5mg

Children 1 month to 4 years: 250 micrograms / kg (maximum 5mg)

It is usually effective within 6 to 12 hours although when used with magnesium citrate for bowel evacuation an effect may be seen within 3 hours.

CONTRAINDICATIONS

It is contraindicated in the following;

- Intestinal obstruction
 - Undiagnosed abdominal pain
 - Acute abdominal conditions such as appendicitis
 - Known hypersensitivity to sodium picosulfate or any other component of the product.
 - Care should be taken in patient with inflammatory bowel disease
 - It should not be used in patient with severe dehydration
- ## WARNINGS AND PRECAUTIONS FOR USE
- As with other laxatives, prolonged used should be avoided
 - When given with other medicines that affect fluids and electrolyte balance
 - Care is needed when sodium picosulfate solution is used with a low seizure threshold or potential sodium depletion
 - Caution is advised with use of bowel cleaning preparations in patients with inflammatory bowel disease

DRUG INTERACTION

The concomitant use of diuretics or adreno-corticosteroids may increase the risk of electrolyte imbalance. However, this situation only arises if excessive doses are taken. Concurrent administration of broad spectrum antibiotics may reduce the laxative action of this product.

ADVERSE EFFECTS

The reported adverse events are diarrhoea, gastrointestinal discomfort, electrolyte imbalance, dehydration, hyponatremia, hypokalaemia, dizziness, nausea, vomiting, syncope, anaphylactoid reactions, angioedema, skin reactions, abdominal discomfort (such as colic and cramps), hematochezia, atonic non-functioning colon and severe bloody diarrhoea may be associated with colonic mucosal ischemia.

SPECIAL WARNINGS

Pregnancy

Nevertheless, medicines should not be used in pregnancy, especially the first trimester, unless the expected benefit is thought to outweigh any possible risk to the foetus.

Lactation

Although the active ingredient is not known to be excreted in breast milk, use of this product during breast feeding is not recommended.

OVERDOSAGE

If high doses are taken diarrhoea, abdominal cramps and a clinically significant loss of potassium and other electrolytes can occur. This may also lead to increased sensitivity to cardiac glycosides. Furthermore, cases of colonic mucosal ischaemia have been reported in association with doses of Sodium Picosulfate considerably higher than those recommended for the routine management of constipation. Laxatives in chronic over dosage are known to cause chronic diarrhoea, abdominal pain, hypokalaemia, secondary hyperaldosteronism and renal calculi. Renal tubular damage, metabolic alkalosis and muscle weakness secondary to hypokalaemia have also been described in association with chronic laxative abuse. Within a short time of ingestion, absorption can be minimized or prevented by inducing

vomiting or by gastric lavage. Replacement of fluids and correction of electrolyte imbalance may be required. This is especially important in the elderly and the young. Administration of antispasmodics may be of some value.

DOSAGE AND INSTRUCTIONS

To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in a dry place. Protect from light.

PRESENTATION

Skilax 5mg Tablets:

Alu. PVC. Blister Pack of 6 x 10's.

Skilax 5mg Tablets:

Alu. PVC. Blister Pack of 3 x 10's.

Skilax Drops:

Pilfer Proof Bottle of 15ml

Skilax Drops:

Pilfer Proof Bottle of 30ml

Pilfer proof plastic bottle.

Do not use if seal is broken.

سکی لیکس®
(سڈیم پیکوسلفیٹ)

خوراک و ہدایات:

صرف مستند ڈاکٹر کے نسخے کے مطابق ہی دوا فروخت اور استعمال کی جائے۔

بچوں کی پہنچ سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔

خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

Manufactured by

HIGHNOON LABORATORIES LTD

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