NAME OF THE MEDICINAL PRODUCT
PICO-SWIFT POWDER FOR ORAL SOLUTION

QUALITATIVE AND QUANTITATIVE COMPOSITION
Each sachet contains:

Sodium Picosulfate	10.0mg
Magnesium Oxide (Heavy)	3.5g
Citric Acid (Anhydrous)	12.0g

LIST OF EXCIPIENTS:
Lactose anhydrous, Potassium Carbonate, Ethanol, Purified Water, Polyvinyl Pyrollidone, Sucralose.

PHARMACEUTICAL FORM
Powder for oral solution in sachet.

THERAPEUTIC INDICATIONS
To clean the bowel prior to X-ray examination or endoscopy.
To clean the bowel prior to surgery when judged clinically necessary (see section Special Warnings and Precautions for Use regarding open colorectal surgery).

POSOLOGY AND METHOD OF ADMINISTRATION
Method of administration
Route of administration: Oral

A low residue diet is recommended on the day prior to the hospital procedure. A clear liquid diet is recommended on the day of the procedure. To avoid dehydration it is important to follow the liquid intake recommendation as advocated together with the PICO-SWIFT dosing whilst the effects of PICO-SWIFT persist (see section Posology). Apart from the liquid intake together with the treatment regimen (PICO-SWIFT + additional liquids), a normal, thirst driven intake of clear liquids is recommended.

Clear liquids should include a variety of fruit juice without pulp, soft drinks, clear soup, tea, coffee (without milk, soy or cream) and water. Do not drink only water.

Posology
Directions for reconstitution:
Reconstitute the Sodium Picosulfate powder right before each administration. Do not prepare the solution in advance. Reconstitute the contents of one sachet in a cup of water (approximately 150ml). Stir for 2-3 minutes, the solution should now become an off-white, cloudy liquid with a

faint odour of orange. Drink the solution. If it becomes warm, wait until it cools sufficiently to drink.

Adults (including the elderly):
(if the procedure is scheduled for the afternoon, it is recommended that the Split-Dose regimen should be used):

Split-Dose Regimen (evening-before and day of the procedure)
The first PICO-SWIFT sachet is taken the night before the procedure, and the second is taken the next day, in the morning prior to the procedure.
On the day before the procedure – 1 sachet:

- The first reconstituted sachet is taken in the evening (e.g. 5:00 to 9:00 PM), followed by at least five 250 ml drinks of clear liquids, spread over several hours.

On the day of the procedure – 1 sachet:

- The second reconstituted sachet is taken in the morning (5-9 hours before the procedure), followed by at least three 250 ml drinks of clear liquids, spread over several hours.
- Clear liquids may be consumed until 2 hours before the time of the procedure.

or

Day-Before Regimen (evening-before the procedure only)
The first PICO-SWIFT sachet is taken in the afternoon or early evening and the second is taken approximately 6 hours later, the night before the procedure.
On the day before the procedure – 2 sachets:

- The first reconstituted sachet is taken in the afternoon or early evening (e.g. 4:00 to 6:00PM), followed by at least five 250 ml drinks of clear liquids, spread over several hours.
- The second reconstituted sachet is taken in the late evening (e.g., 10:00PM to 12:00AM), followed by at least three 250 ml drinks of clear liquids, spread over several hours.
- Clear liquids may be consumed until 2 hours before the time of the procedure.

Paediatric population:
The safety and efficacy of Sodium picosulfate in paediatric patients has not been established.

CONTRAINDICATIONS
- Hypersensitivity to any of the ingredients of the product
- Congestive cardiac failure
- Gastric retention
- Gastro-intestinal ulceration
- Toxic colitis
- Toxic megacolon
- Ileus

- Nausea and vomiting
- Acute surgical abdominal conditions such as acute appendicitis
- Known or suspected gastro-intestinal obstruction or perforation.
- Severe dehydration
- Rhabdomyolysis
- Hypermagnesemia
- Active inflammatory bowel disease
- In patients with severely reduced renal function, accumulation of magnesium in plasma may occur. Another preparation should be used in such cases.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Because a clinically relevant benefit of bowel cleansing prior to elective, open colorectal surgery could not be proven, bowel cleansers should only be administered before bowel surgery if clearly needed. The risks of the treatment should be carefully weighed against possible benefits and needs depending on surgical procedures performed.

Care should also be taken in patients with recent gastro-intestinal surgery, renal impairment, heart disease or inflammatory bowel disease.

Use with caution in patients on drugs that might affect water and/or electrolyte balance e.g. diuretics, corticosteroids, lithium (see section Interaction with Other Medicinal Products and Other Forms of Interactions).

Advise patients to hydrate adequately before, during, and after the use of PICO-SWIFT. An insufficient or excessive oral intake of water and electrolytes could create clinically significant, deficiencies, particularly in less fit patients. In this regard, children, the elderly, debilitated individuals and patients at risk of hypokalaemia or hyponatremia may need particular attention. Prompt corrective action should be taken to restore fluid/electrolyte balance in patients with signs or symptoms of hypokalaemia or hyponatremia. Drinking only water to replace the fluid losses may lead to electrolyte imbalance.

PICO-SWIFT may modify the absorption of regularly prescribed oral medication and should be used with caution e.g. there have been isolated reports of seizures in patients on antiepileptics, with previously controlled epilepsy (see section Interaction with Other Medicinal Products and Other Forms of Interactions and Undesirable Effects).

Use caution when prescribing PICO-SWIFT for patients with a history of seizures and in patients at risk of seizure, such as patients taking medications that lower the seizure threshold (e.g., tricyclic antidepressants), patients withdrawing from alcohol or benzodiazepines, patients with known or suspected hyponatremia.

There have been rare reports of serious arrhythmias associated with the use of ionic osmotic laxative products for bowel preparation. Use caution when prescribing PICO-SWIFT for patients at increased risk of arrhythmias (e.g., patients with a history of prolonged QT, uncontrolled arrhythmias, recent myocardial infarction, unstable angina, congestive heart failure, or cardiomyopathy).

Osmotic laxatives may produce colonic mucosal aphthous ulcerations and there have been reports of more serious cases of ischemic colitis requiring hospitalization. Concurrent use of additional stimulant laxatives with PICO-SWIFT may increase this risk. The potential for mucosal ulcerations should be considered when interpreting colonoscopy findings in patients with known or suspected inflammatory bowel disease.

Patients with impaired gag reflex and patients prone to regurgitation or aspiration should exercise caution during the administration of PICO-SWIFT.

The period of bowel cleansing should not exceed 24 hours because longer preparation may increase the risk of water and electrolyte imbalance.

This medicine contains 282.89 mg potassium per sachet. This should be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.
This medicine contains lactose as a component of the flavour. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

PICO-SWIFT should not be used as a routine laxative.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS

As a purgative, PICO-SWIFT increases the gastrointestinal transit rate. The absorption of other orally administered medicines (e.g. anti-epileptics, contraceptives, anti-diabetics, antibiotics) may therefore be modified during the treatment period (see section Special Warnings and Precautions for Use). Oral medication administered within one hour of the start of administration of PICO-SWIFT solution may be flushed from the GI tract and the medication may not be absorbed. Tetracycline and fluoroquinolone antibiotics, iron, digoxin, chlorpromazine and penicillamine, should be taken at least 2 hours before and not less than 6 hours after administration of PICO-SWIFT to avoid chelation with magnesium.

The efficacy of PICO-SWIFT is lowered by bulk-forming laxatives.

Prior or concomitant use of antibiotics with PICO-SWIFT may reduce efficacy of PICO-SWIFT as conversion of sodium picosulfate to its active metabolite BHPM is mediated by colonic bacteria.
Use caution when prescribing PICO-SWIFT for patients with conditions or who are using medications that increase the risk for fluid and electrolyte disturbances or may increase the risk of seizure, arrhythmias, and prolonged QT in the setting of fluid and electrolyte abnormalities. This includes patients receiving drugs which may be associated with hypokalaemia (such as diuretics or corticosteroids, or drugs where hypokalaemia is a particular risk i.e. cardiac glycosides). Caution is also advised when PICO-SWIFT is used in patients on NSAIDs or drugs known to induce Syndrome of Inappropriate Antidiuretic Hormone Secretion (SIADH) e.g. tricyclic antidepressants, selective serotonin re-uptake inhibitors, antipsychotic drugs and carbamazepine as these drugs may increase the risk of water retention and/or electrolyte imbalance.

FERTILITY, PREGNANCY AND LACTATION

Pregnancy

For Sodium Picosulfate no clinical data on exposed pregnancy are available. Studies in animals have shown reproductive toxicity. As picosulfate is a stimulant laxative, for safety measure, it is preferable to avoid the use of Sodium Picosulfate during pregnancy.

Fertility

Studies with Sodium Picosulfate in animals have shown no impairment of fertility or embryo-fetal toxicity. In studies with sodium picosulfate alone, embryofetal toxicity has been observed in rats and rabbits at very high doses (see section Preclinical Safety Data).

Breastfeeding

There is no experience with the use of Sodium Picosulfate in nursing mothers. It is not known whether this drug is excreted in human milk. It is advised to exercise caution when Sodium Picosulfate is administered to a nursing woman.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Not applicable.

UNDESIRABLE EFFECTS

The most frequent adverse reactions seen in clinical trials are nausea, headache, abdominal pain and vomiting. Hyponatraemia is rare, but is the most commonly reported serious adverse reaction. Adverse reactions from spontaneous reports are presented by frequency category based on incidence in clinical trials when known. Frequency from spontaneous reports for adverse reactions never observed in clinical trials is based on an algorithm as recommended in the European Commission SmPC guideline, 2009, rev 2.

MedDRA Organ Class	**Common (≥1/100 to <1/10)**	**Uncommon (≥1/1000 to <1/100)**	**Rare (≥1/10.000 to <1/1000)**
Immune system disorder		Anaphylactic reaction, Hypersensitivity	
Metabolism and nutrition disorders	Hypermagnesaemia	Hypokalaemia	Hyponatraemia
Nervous system disorders	Headache	Epilepsy, Generalised tonic-clonic seizure[a], Seizure[b], Loss of or depressed level of consciousness Syncope Dizziness Confusional state including Disorientation	Presyncope
Gastrointestinal disorders	Vomiting, Nausea, Abdominal pain	Diarrhoea[c]	Ileal ulcers[d] Anal incontinence[e], Proctalgia
Skin and subcutaneous tissue disorders		Rash (including erythematous rash, maculo-papular rash, urticaria, purpura)	

a Defined as grand mal convulsion in previous MedDRA versions. In epileptic patients, there have been isolated reports of seizure/generalised tonic-clonic seizure without associated hyponatraemia.

b Defined as convulsions in previous MedDRA versions.

c Isolated cases of severe diarrhoea have been reported post-marketing.

d Isolated cases of mild reversible aphthoid ileal ulcers have been reported.

e Defined as faecal incontinence in previous MedDRA versions.

OVERDOSE

Overdose would lead to profuse diarrhoea. Treatment is by general supportive measures and correction of fluid and electrolyte balance.

PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Contact Laxatives
ATC code: A06A B58

Mechanism of action

Sodium picosulfate is hydrolyzed by colonic bacteria to form an active metabolite: bis-(p-hydroxyphenyl)-pyridyl-2-methane (BHPM), which acts directly on the colonic mucosa to stimulate colonic peristalsis.
Magnesium oxide and citric acid react to create magnesium citrate in solution, which is an osmotic agent that causes water to be retained within the gastrointestinal tract.

Pharmacodynamic effects

The stimulant laxative activity of sodium picosulfate together with the osmotic laxative activity of magnesium citrate produces a purgative effect which, when ingested with additional fluids, produces watery diarrhea that clear the bowel.
The product is not intended for use as a routine laxative.

PHARMACOKINETIC PROPERTIES

Absorption

Sodium picosulfate, which is a prodrug, is converted to its active metabolite, BHPM, by colonic bacteria.
After administration of 2 sachets of PICOPREP separated by 6 hours, in 16 healthy subjects, sodium picosulfate reached a mean Cmax of 3.2 ng/mL at a median 8 hours (Tmax). After the first sachet, the corresponding value was 2.3 ng/mL at 2 hours. Magnesium oxide and citric acid react in solution to create magnesium citrate. Magnesium concentration value not corrected for baseline were 0.88 and 0.95 mmol/L at 4 and 10 hours, respectively. The baseline value was 0.75 mmol/L.

Distribution

The apparent volume (V/F) of sodium picosulfate was 3910 liters.

Biotransformation and Elimination

The fraction of the sodium picosulfate dose excreted unchanged in urine was 0.11%. Plasma levels of BHPM were low with 13 out of 16 subjects studied having plasma BHPM concentrations below the lower limit of quantification (0.1 ng/mL). Urinary samples show that

the majority of excreted BHPM was in the glucuronide-conjugated form. The apparent clearance (CL/F) of sodium picosulfate was 463 L/h. The terminal half-life of sodium picosulfate was 7.4 hours.

Clinical studies in bowel cleansing before colonoscopy have shown an increase from baseline to colonoscopy visit in serum magnesium of approximately 0.11 mmol/L (from 0.86 to 0.97 mmol/L). All changes in serum magnesium were transient and within normal limits, including in patients with mild to moderate renal impairment.

PRECLINICAL SAFETY DATA

Non-clinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity and genotoxicity.

Due to the very short treatment duration no long-term studies in animals have been performed. Reproductive studies have shown no potential for impairment of fertility or harm to the foetus for sodium picosulfate and Sodium Picosulfate.

In a study on pre- and postnatal development, the NOAEL of Sodium Picosulfate was the mid dose of 750 mg/kg BID. The adverse effect that occurred in the 2000 mg/kg BID group (approximately 8 times the recommended human dose), was pup mortality, between lactation days 2 to 4 due to maternal toxicity.

Effects in reproductive and developmental toxicity studies with sodium picosulfate alone were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

INCOMPATIBILITIES
Not applicable.

SHELF-LIFE
36 months

SPECIAL PRECAUTIONS FOR STORAGE
Store below 30°C.

NATURE AND CONTENTS OF CONTAINER
Powder for Oral Solution is packed in printed four layer laminated paper foil sachet. Such 2 sachets are packed in a carton along with Insert.

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING
No special requirements.

MANUFACTURER

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