Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Picolax 10mg / 3.5g / 12 g Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

Sodium Picosulfate	10 mg
Magnesium Oxide	3.5 g
Citric Acid	12 g

Each sachet also contains:
Potassium hydrogen carbonate 0.5g [equivalent to 5 mmol (195 mg) potassium]
Lactose (60 mg flavour contains 7.5% lactose which equals 4.5 mg per dosage form)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution
White crystalline powder

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For evacuation of the bowel prior to radiological, endoscopic or surgical procedures.

4.2 Posology and method of administration

Method of administration
Route of administration: Oral.

A low residue diet is recommended on the day prior to the 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 Picolax dosing while the effects of Picolax persist (see section 4.2, Posology). Apart from the liquid intake together with the treatment regimen (Picolax + 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. Liquid intake should not be restricted to only drinking water.

Posology

Directions for reconstitution:
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 elderly):
The first Picolax sachet is taken before 8 am the day before the procedure and the second is taken 6 to 8 hours later.

On the day before the procedure – 2 sachets:

- The first reconstituted sachet is taken before 8 am, followed by at least 5x 250 ml drinks of clear liquids (not only water), spread over several hours

- The second reconstituted sachet is taken 6 to 8 hours later, followed by at least 3x 250 ml drinks of clear liquids (not only water), spread over several hours
- Clear liquids (not only water) may be consumed until 2 hours before the time of the procedure.

Children:

The first dose reconstituted in water as directed, taken before 8 am on the day before the procedure. Second dose 6 to 8 hours later.

from 1 up to 2 years: ¼ sachet morning, ¼ sachet afternoon

from 2 up to 4 years: ½ sachet morning, ½ sachet afternoon

from 4 up to 9 years: 1 sachet morning, ½ sachet afternoon

9 and above: adult dose

Maintaining hydration in children is very important. Guidelines for treating dehydration in children should be followed to ensure adequate hydration during treatment with Picolax.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1
- Congestive cardiac failure
- Gastric retention
- Gastro-intestinal ulceration
- Toxic colitis
- Toxic megacolon
- Ileus
- Severe 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.

Not to be administered to unconscious patients or those with impaired consciousness, general weakness and patients with a tendency to aspiration or regurgitation or impaired swallowing reflex.

4.4 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.

An insufficient or excessive oral intake of water and electrolytes could create clinically significant abnormalities, particularly in less fit patients. In this regard, children, the elderly, debilitated individuals and patients at risk of hypokalaemia or hyponatraemia may need particular attention. Prompt corrective action should be taken to restore fluid/electrolyte balance in patients with signs or symptoms of hypokalaemia or hyponatraemia.

Drinking only water to replace the fluid losses may lead to electrolyte imbalance, which may in severe cases lead to complications such as seizures and coma. In rare cases, Picolax can cause severe or life-threatening electrolyte problems or impaired renal function in fragile or debilitated patients.

Few episodes of severe hypermagnesaemia have been reported following the use of Picoprep. In the majority of the cases this occurred in association with other factors (e.g. renal impairment or concomitant medication).

Care should 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 4.5).

Picolax 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 4.5 and 4.8).

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 5 mmol (or 195 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.

Picolax should not be used as a routine laxative.

4.5 Interaction with other medicinal products and other forms of interaction

As a purgative, Picolax increases 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 4.4).

Medicines with the potential to chelate with magnesium (e.g. tetracycline and fluroquinolone antibiotics, iron, digoxin, chlorpromazine and penicillamine) should be taken not later than 2 hours before and within 6 hours following administration of Picolax.

The efficacy of Picolax is lowered by bulk-forming laxatives.

Care should be taken with patients already 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 Picolax is used in patients on NSAIDS or drugs known to induce 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.

4.6 Fertility, pregnancy and lactation

For Picolax no clinical data on exposed pregnancy are available. Studies with Picolax in animals have shown no impairment of fertility or embry-fetal toxicity. In studies with sodium picosulfate alone, embryofetal toxicity has been observed in rats and rabbits at very high doses (see section 5.3). Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.
There is no experience with the use of Picolax in nursing mothers, so the drug should only be used in nursing mothers if clearly needed.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

The most common adverse reactions are vomiting, nausea, abdominal pain and headache. Hyponatremia 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 (≥1/10000 to ≤1/1000)**
Immune system disorders		Anaphylactic reaction, hypersensitivity	
Metabolism and nutrition disorders	Hypermagnesaemia	Hypokalaemia	Hyponatraemia
Psychiatric disorders		Confusional state including disorientation	
Nervous system disorders	Headache	Epilepsy, Generalised tonic-clonic seizure[a], Seizure, Loss of or depressed level of consciousness, Syncope, Dizziness	Presyncope
Gastrointestinal disorders	Vomiting, nausea, abdominal pain	Diarrhoea[b]	Ileal ulcer[c], anal incontinence, proctalgia
Skin and subcutaneous tissue disorders		Rash (including erythematous rash, maculo-papular rash, urticaria, purpura)	

[a] In epileptic patients, there have been isolated reports of seizure/grand mal convulsion without associated hyponatraemia.
[b] Isolated cases of severe diarrhoea have been reported post-marketing.
[c] Isolated cases of mild reversible aphthoid ileal ulcers have been reported.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Contact laxatives
ATC Code: AO6A B58

The active components of Picolax are sodium picosulfate and magnesium citrate. Sodium picosulfate is a locally acting stimulant cathartic, which after bacterial cleavage in the colon forms the active laxative compound, bis-(p-hydroxyphenyl)-pyridyl-2-methane(BHPM), which has a dual-action with stimulation of the mucosa of both the large intestine and of the rectum.
Magnesium citrate acts as an osmotic laxative by retaining moisture in the colon. The combined action of the two substances is of a 'washing out' effect combined with peristaltic stimulation to clear the bowel.
The product is not intended for use as a routine laxative.

5.2 Pharmacokinetic properties

Sodium picosulfate and magnesium citrate, the two components of Picolax, are locally active with minimal systemic exposure.

After administration of Picolax (2 sachets separated by 6 hours), picosulfate reached mean levels of 2.3 and 3.2 ng/mL (Cmax) at a median of 2 and 8 hours (Tmax) after the first and second sachet, respectively. The corresponding values for magnesium were 0.90 and 0.95 mmol/L at 4 and 10 hours, respectively. The baseline value was 0.75 mmol/L.

The mean terminal half-life of picosulfate was 7.4 hours. The fraction of the sodium picosulfate dose excreted unchanged in urine was 0.11%. Plasma levels of BHPM were consistently low or undetectable and urinary samples showed that the majority of excreted BHPM was the glucuronide-conjugated form.

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.

5.3 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 Picolax.

In a study on pre- and postnatal development, the NOAEL of Picolax 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium hydrogen carbonate
Saccharin Sodium
Natural, spray dried organge flavour which contains acacia gum, lactose, ascorbic acid, butylated hydroxyanisole

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of unopened sachets: 3 years.

Once the sachet has been opened, use immediately and discard any unused powder or solution.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

The powder is supplied in unit dose sachets each containing 16.1 g. Double sachets divided by a tear-off perforation are packed in cartons of 1 x 2 sachets and 25 x 2 sachets. The sachet is made from a four layer foil of paper-polyethylene-aluminium-surlyn. The surlyn layer is in contact with the powder.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Ferring Ireland Ltd
United Drug House
Magna Drive, Magna Business Park
Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1009/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th February 1983
Date of last renewal: 24th February 2008

10 DATE OF REVISION OF THE TEXT

March 2026