Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sodium Picosulfate Ferring 5mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains

5 mg sodium picosulfate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

White to off-white round tablets, 6 mm in diameter, debossed with 5.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Short term relief of functional constipation.

Sodium Picosulfate Ferring is indicated in adults and in children aged from 10 years.

4.2 Posology and method of administration

Posology
Adults and children from 10 years of age
One to two tablets (5 – 10mg) swallowed whole at bedtime.
Dosage can be titrated individually. Once regularity has re-started dosage should be reduced and can usually be stopped.

Sodium Picosulfate Ferring should not be taken every day for more than five days without investigating the cause of constipation.

Paediatric population
Sodium Picosulfate Ferring should not be used in children below 10 years of age.

The safety and efficacy of Sodium Picosulfate Ferring in children below 10 years of age have not been established. No data are available.

Method of administration
The tablet should be swallowed whole with adequate fluid.

The maintenance of an adequate fluid intake during treatment is essential, especially for younger patients and the elderly who are more susceptible to the effects of dehydration.

4.3 Contraindications

Sodium Picosulfate Ferring is contraindicated in patients with ileus, gastrointestinal obstruction, gastrointestinal ulceration or perforation, acute abdominal surgical conditions including appendicitis, acute inflammatory bowel diseases, and severe abdominal pain associated with nausea and vomiting which may be indicative of the aforementioned severe conditions.

Sodium Picosulfate Ferring is also contraindicated in severe dehydration and in patients with hypersensitivity to the active substance or to any of the excipients.

Furthermore, Sodium Picosulfate Ferring should not be used in case of sudden, severe abdominal pain just before intake, undiagnosed rectal bleeding and acute hepatic failure.

4.4 Special warnings and precautions for use

- Prolonged excessive use of Sodium Picosulfate Ferring may lead to fluid and electrolyte imbalance and hypokalaemia.
- Care should be taken in patients with recent gastro-intestinal surgery and in patients with renal impairment, heart disease or inflammatory bowel disease.
- Sodium Picosulfate Ferring should be used with caution in patients on drugs that might affect water and/or electrolyte balance e.g. diuretics, corticosteroids, lithium (see section 4.5).
- Sodium Picosulfate Ferring may modify the absorption of regularly prescribed oral medication and should be used with caution (see section 4.5).
- Long term use of stimulant laxatives could induce a cathartic colon.

4.5 Interaction with other medicinal products and other forms of interaction

- The concomitant use of diuretics or adreno-corticosteroids may increase the risk of electrolyte imbalance if excessive doses of Sodium Picosulfate Ferring are taken.
- Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides or increased risk of lithium toxicity.
- Concurrent administration of antibiotics may reduce the laxative action of Sodium Picosulfate Ferring.
- Sodium Picosulfate Ferring may increase 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 4.4).
- Caution is advised when Sodium Picosulfate Ferring 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 Sodium Picosulfate Ferring no clinical data on exposed pregnancy are available. Reproduction studies with sodium picosulfate performed in animals have revealed no evidence of teratogenic potential. However, embryofetal toxicity has been observed in rats and rabbits at high doses (see section 5.3). Therefore, Sodium Picosulfate Ferring should not be taken during pregnancy unless the expected benefit is thought to outweigh any possible risk and only on medical advice.

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. Nevertheless, as with all medicines, Sodium Picosulfate Ferring should not be taken during breast feeding unless the expected benefit is thought to outweigh any possible risk and only on medical advice.

4.7 Effects on ability to drive and use machines

Sodium Picosulfate Ferring has no or negligible influence on ability to drive and use machines.

4.8 Undesirable effects

Adverse events have been ranked under headings of frequency using the following convention:
Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1000 to <1/100); rare (≥ 1/10000 to <1/1000); very rare (<1/10000).

MedDRA Organ Class	**Common (≥1/100 to ≤1/10)**	**Uncommon (≥1/1000 to ≤1/100)**	**Rare (≥1/10000 to ≤1/1000)**	**Not known (cannot be estimated from the available data)**
Immune system disorders			Hypersensitivity (incl. angioneurotic oedema and skin reactions)	
Gastrointestinal disorders	Abdominal discomfort, abdominal pain, abdominal cramps, and diarrhoea	Nausea and vomiting		Flatulence
Nervous system disorders				Headache, dizziness, vertigo and syncope

4.9 Overdose

Symptoms: If high doses are taken diarrhoea, abdominal cramps and a clinically significant loss of potassium and other electrolytes can occur.

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 when taken in chronic overdosage may 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.

Therapy: Within a short time of ingestion, absorption can be minimised 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Laxatives; Contact laxatives

ATC code: A06AB08

Sodium picosulfate, the active ingredient of Sodium Picosulfate Ferring, is a locally acting laxative from the triarylmethane group, which after bacterial cleavage in the colon, has a dual-action with stimulation of the mucosa of both the large intestine and of the rectum. Stimulation of the mucosa of the large intestine results in colonic peristalsis, with promotion of accumulation of water, and consequently electrolytes, in the colonic lumen. This results in a stimulation of defecation, reduction of transit time and softening of the stool.

The onset of action of the preparation is usually between 6 - 12 hours, which is determined by the release of the active ingredient.

5.2 Pharmacokinetic properties

After oral ingestion, sodium picosulfate reaches the colon without any appreciable absorption. Therefore, enterohepatic circulation is avoided. The active laxative compound, bis-(p-hydroxyphenyl)-pyridyl-2-methane (BHPM), is formed by bacterial cleavage in the intestine.

The main part of the dose is recovered as parent compound or metabolites in faeces after administration.

After oral administration, only small amounts of the drug are systemically available.

There is no relationship between the laxative effect and plasma levels of the active moiety.

5.3 Preclinical safety data

Published animal data suggest no special hazards for humans with regard to unwanted pharmacological effects, and toxicity following repeat doses. In vitro and in vivo studies indicated no genotoxic potential. No animal carcinogenicity studies have been performed.

Reproductive toxicity studies in rats and rabbits did not reveal any teratogenic potential after oral dosing of sodium picosulfate up to 10000 and 1000 mg/kg/day, respectively. Embryo-foetal toxicity was apparent in rats and rabbits at 1000 mg/kg /day, manifested as lower foetal weight and an increase in resorptions in rabbits. In rats, daily doses of 10 mg/kg and 100 mg/kg during late gestation (fetal development) and lactation reduced body weight gain of the offspring. At 100 mg/kg there was also an increased number of dead pups at birth. Male and female rat fertility was not affected by oral doses of sodium picosulfate up to 100 mg/kg.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose, microcrystalline (E460)
Maize starch
Silica, colloidal anhydrous
Magnesium stearate (E470b)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Packed in PVC/PE/PVDC/Aluminium blister
Pack sizes: 2 and 10 tablets
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

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

PA 1009/24/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 4th November 2011

10 DATE OF REVISION OF THE TEXT

September 2012