Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dulcolax Pico Perles 2.5 mg Capsules, soft

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft capsule contains 2.5 mg sodium picosulfate as Sodium Picosulfate Monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, soft
Round, colourless, clear capsule.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the short term management of constipation.

4.2 Posology and method of 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.

Adults and children over 10 years of age
Two to four capsules (5 - 10 mg) per day.

Children under 10 years of age
Not to be taken by children under 10 years of age without medical advice.

Children aged 4 - 10 years
One to two capsules (2.5 - 5 mg) per day.

Children under 4 years of age
Not recommended for children under 4 years of age.

Once regularity has been restarted, dosage should be reduced and can usually be stopped.

The capsules should be swallowed with adequate fluid.

4.3 Contraindications

DULCOLAX PICO is contraindicated in patients with:

- 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
- Rare hereditary conditions that may be incompatible with an excipient of the product (see section 4.4).

4.4 Special warnings and precautions for use

As with all laxatives, Dulcolax Pico Perles should not be taken on a continuous daily basis for more than five days without investigating the cause of constipation.

Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalaemia.

Dizziness and/or syncope have been reported in patients who have taken products in the DULCOLAX or DULCOLAX PICO ranges. The details available for these cases suggest that the events would be consistent with defaecation syncope (or syncope attributable to straining at stool), or with a vasovagal response to abdominal pain related to the constipation, and not necessarily to the administration of sodium picosulfate itself.

Dulcolax Pico Perles should not be taken by children under 10 years without medical advice.

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 Dulcolax Pico Perles are taken.

Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

Concurrent administration of antibiotics may reduce the laxative action of this product.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate and well-controlled studies in pregnant women. Long experience has shown no evidence of undesirable or damaging effects during pregnancy.

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.

Nevertheless, as with all medicines, DULCOLAX PICO should not be taken in pregnancy, especially the first trimester, and during breast feeding unless the expected benefit is thought to outweigh any possible risk and only on medical advice.

Fertility
No studies on the effect on human fertility have been conducted. Non-clinical studies did not reveal any effect on fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

However, patients should be advised that due to a vasovagal response (for example, due to abdominal spasm), dizziness and /or syncope may be experienced. If patients experience abdominal spasm they should avoid potentially hazardous tasks such as driving or operating machinery.

4.8 Undesirable effects

Adverse events have been ranked under headings of frequency using the following convention: Very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1000, <1/100); rare (≥ 1/10000, <1/1000); very rare (<1/10000); not known – cannot be estimated from the available data.

Immune system disorders
Not known: Hypersensitivity*

Nervous system disorders
Uncommon: Dizziness
Not known: Syncope*
Dizziness and syncope occurring after taking sodium picosulfate appear to be consistent with a vasovagal response (for example, due to abdominal spasm, defaecation).

Gastrointestinal disorders
Very common: Diarrhoea
Common: Abdominal discomfort, abdominal pain, abdominal cramps.
Uncommon: Nausea, vomiting.

Skin and subcutaneous tissue disorders
Not known: Skin reactions* such as angioedema*, drug eruption*, rash*, pruritus*.

*This adverse event has been observed in post-marketing experience. With 95% certainty, the frequency category is not greater than uncommon, but might be lower. A precise frequency estimation is not possible as the adverse event did not occur in a clinical trial database of 1020 patients.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

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

Furthermore, cases of colonic mucosal ischaemia have been reported in association with doses of DULCOLAX PICO range 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: Laxative
ATC code: A06AB08

Sodium picosulfate 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 defaecation, 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” although its clinical relevance remains to be established.

As a laxative that acts on the colon, sodium picosulfate specifically stimulates the natural evacuation process in the lower region of the gastrointestinal tract. Therefore, sodium picosulfate is ineffective in altering the disgestion or absorption of calories or essential nutrients in the small intestine.

5.2 Pharmacokinetic properties

Absorption and Distribution
After oral ingestion, sodium picosulfate reaches the colon without any appreciable absorption. Therefore, enterohepatic circulation is avoided.

Biotransformation
Sodium picosulfate is converted into the active laxative compound, bis-(p-hydroxyphenyl)-pyridyl-2-methane (BHPM), via bacterial cleavage in the distal segment of the intestine.

Elimination
Following conversion, only small amounts of BHPM are absorbed and are almost completely conjugated in the intestinal wall and the liver to form the inactive BHPM glucuronide. After oral administration of 10 mg sodium picosulfate 10.4% of the total dose was excreted as BHPM glucuronide in urine after 48 hours. In general, urinary excretion decreases when higher doses of sodium picosulfate are being administered.

Pharmacokinetic/Pharmacodynamic relationship(s)
Consequently, the onset of action of the preparation is usually between 6 - 12 hours, which is determined by the release of the active substance (BHPM).
There is no direct or inverse relationship between the laxative effect and plasma levels of the active moiety.

5.3 Preclinical safety data

Sodium picosulfate was investigated for teratogenicity (Segment II) in rats (1, 10, 1000 and 10000 mg/kg) and rabbits (1, 10 and 1000 mg/kg) following oral dosing. Maternal toxic dose levels causing severe diarrhoea were associated with embryotoxicity (increase of early resorptions) without any teratogenic effects or adverse effects on the reproductive performance of the offspring. Fertility and general embryonic development (Segment I) as well as pre-and postnatal development (Segment III) of rats were not impaired by oral doses of 1, 10 and 100 mg/kg.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Macrogol 400
Gelatin
Glycerol
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

Keep the bottle within the outer carton, in order to protect from light.

6.5 Nature and contents of container

Type III colourless glass bottles with polypropylene screw caps or child resistant polypropylene screw caps.
Pack sizes 20, 24, 30, 40 or 50 capsules.
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.
Any unused product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Sanofi-Aventis Ireland Ltd
T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0540/183/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1999

Date of last renewal: 01 April 2009

10 DATE OF REVISION OF THE TEXT

August 2017