Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dulcolax Pico Liquid 5 mg/5 ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Oral solution containing 5 mg of sodium picosulfate (as monohydrate) in each 5 ml.

Excipients:
Methyl Parahydroxybenzoate (E218) 2.5 mg / 5 ml
Propyl Parahydroxybenzoate (E216) 0.5 mg / 5 ml
Ethanol 96% 250 mg / 5 ml

Excipient with known effect: Each 5 ml dose contains 1.18 mg sodium.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution
Clear, colourless to yellowish or slightly yellowish-brown, slightly viscous liquid.

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:
One to two 5 ml spoonfuls (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:
Half to one 5 ml spoonful (2.5-5 mg) per day.

Children aged 2-4 years:
The recommended dosage is 0.25 mg per kilogram body weight per day (1 ml of Dulcolax Pico Liquid contains 1 mg sodium picosulfate).
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In the management of constipation, once regularity has been restarted dosage should be reduced and can usually be stopped.

Diluent: Can be diluted with purified water.

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 Liquid 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 Liquid should not be taken by children under 10 years without medical advice.

Dulcolax® Pico Liquid contains 480mg of alcohol (ethanol) in each 10ml dose which is equivalent to 4.8 w/v%. A daily dose of 1 – 2 5 ml spoonfuls of this medicine is equivalent to 5.2 - 10.4 ml of 5% beer and to 2.2 - 4.3 ml of 12% wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Dulcolax Pico Liquid contains the preservatives methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) per 10ml dose, that is to say essentially 'sodium-free'.

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 Liquid are taken.

Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

Concurrent administration ofantibiotics 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 thefollowing convention:
Very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1000, <1/100); rare (≥ 1/10000, <1/1000); very rare (<1/10000); notknown – 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 appearto 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 products in the 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 digestion 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

Carmellose sodium
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Glycerol
Tutti Frutti Flavour
Saccharin sodium
Ethanol
Sodium hydroxide (for pH adjustment only)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Keep container in the outer carton.

6.5 Nature and contents of container

30 ml, 100 ml, 250 ml and 300 ml amber glass (Type III) bottles with polypropylene tamper-evident closure with expanded polyethylene (coated with LDPE) liner.

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

Opella Healthcare, France SAS, 157 avenue Charles de Gaulle, 92200 Neuilly-sur-Seine, France

8 MARKETING AUTHORISATION NUMBER

PA23180/017/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31 August 1975

Date of last renewal: 01 March 2008

10 DATE OF REVISION OF THE TEXT

Novemeber 2023