SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dulcolax® Adult Pico Liquid, 5 mg / 5 ml, oral solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of liquid contains 5 mg sodium picosulfate.

Dulcolax® Pico Liquid also contains methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), ethanol and the colouring agent sunset yellow FCF (E110).

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.

Golden orange coloured liquid, with a fruit-like odour and taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the short-term relief of occasional 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*:* One to two 5 ml spoonfuls (5 - 10 mg) per day.

Should not be used in children or adolescents under the age of 18 years.

In the management of constipation, once regularity has 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

Should not be used in children or adolescents under the age of 18 years.

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

Long-term everyday use of stimulant laxatives may harm the intestinal function and should be avoided. If laxatives are needed every day the cause of the constipation should be investigated. This product should only be used if a therapeutic effect cannot be achieved by a change of diet or the administration of bulk forming agents.

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

Intestinal loss of fluids can promote dehydration. Symptoms may include thirst and oliguria. In patients suffering from fluid loss where dehydration may be harmful (e.g. renal insufficiency, elderly patients) sodium picosulfate should be discontinued and only be restarted under medical supervision.

Stimulant laxatives (including sodium picosulfate) do not help with weight loss.

If symptoms worsen during the use of the medicinal product, a doctor or pharmacist should be consulted.

Dizziness and/or syncope have been reported in patients who have taken Dulcolax. 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 contains 4.8 vol % ethanol (alcohol) i.e. up to 480 mg per dose, equivalent to 10.4 ml beer, 4.3 ml wine per dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

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

The leaflet will state:

"Before you take this medicine" section

Does this help with weight loss?

Stimulant laxatives (including sodium picosulfate) do not help with weight loss. They do not reduce the absorption of calories or nutrients. They can cause watery stools (diarrhoea), abdominal cramps and dehydration. Dehydration can seem like weight loss.

Overuse of laxatives may damage your health by:

- Causing disturbances of electrolyte and mineral balances. Sodium, potassium, magnesium, and phosphorus are electrolytes and minerals that are present in very specific amounts necessary for proper functioning of the nerves and muscles, including those of the colon and heart. Upsetting this delicate balance can cause incorrect functioning of these vital organs.
- Severe dehydration may cause tremors, weakness, blurry vision, fainting, kidney damage, and, in extreme cases, death. Dehydration often requires medical treatment.
- Overuse of laxatives must be avoided as it may harm the intestinal function.

The label will state:

Front of pack:

- Does not help with weight loss
- Overuse can be harmful

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 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store.

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 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 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 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 maternotoxic (severe diarrhoea) in rats and rabbits at exposures ≥ 810- fold above the maximum recommended human daily dose [MRHDD] based on mg/m^2. Embryotoxicity (increased incidence of early resorptions) was observed at maternotoxic doses in rats and rabbits and was considered secondary to maternotoxicity. There were no other reported effects on

embryofetal development, pre- and postnatal development and fertility parameters at exposures up to 81-fold above the MRHDD based on mg/m^2.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Carboxymethylcellulose

Methyl Parahydroxybenzoate (E218)

Propyl Parahydroxybenzoate (E216)

Glycerol

Aroma Tutti Frutti (flavouring)

Saccharin Sodium

FD & C Yellow 6 (E110) (colouring)

Ethanol 96%

0.1 M Sodium Hydroxide

Purified Water

6.2 Incompatibilities

None stated

6.3 Shelf life

3 years

6.4 Special precautions for storage

Keep the container in the outer carton

6.5 Nature and contents of container

Amber glass bottles with aluminium ROPP caps.
Pack sizes of 30, 40, 50, 60 and 100 ml.

Amber glass bottles with polypropylene tamper-evident closure with expanded Polyethylene (coated with LDPE) liner.

Pack size of 30 ml and 100 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable.

7. MARKETING AUTHORISATION HOLDER

Aventis Pharma Limited, trading as Sanofi
410 Thames Valley Park Drive,
Reading,
Berkshire,
RG6 1PT,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 04425/0731

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31/03/2016

10 DATE OF REVISION OF THE TEXT

06/03/2020