

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Picosulfate 5mg/5ml Oral Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient: Sodium picosulfate.

The solution contains 5mg of sodium picosulfate in each 5ml.

Excipients of known effect:

Each 5 ml contains: 10mg of sodium methyl parahydroxybenzoate (E219), 0.7mg of sodium propyl parahydroxybenzoate (E217), 1250mg of liquid maltitol (E965), 0.125mg of sunset yellow (E110) and 0.07mg of carmoisine (E122).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.

A clear 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

Posology

Unless otherwise prescribed by the doctor, the following dosage is recommended:

Adults and children over 12 years:

One to two 5ml spoonfuls (5 -10mg) per day

Should not be used in children and adolescents under the age of 12 years.

In the management of constipation, once regularity has restarted dosage should be reduced and can usually be discontinued.

Diluent: Can be diluted with purified water.

Method of administration:

For oral use.

4.3 Contraindications

Not to be used in patients with ileus, intestinal obstruction, acute surgical abdominal conditions like acute appendicitis, acute inflammatory bowel diseases, and severe abdominal pain associated with nausea and vomiting which may be indicative of the aforementioned severe conditions, and in severe dehydration.

Not to be used in patients with a known hypersensitivity to sodium picosulfate or any other component of the product.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.4 Special warnings and precautions for use

As with all laxatives, Sodium Picosulfate Oral Solution 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 the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted.

Dizziness and/or syncope have been reported in patients who have taken sodium picosulfate. 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.

Should not be used in children and adolescents under the age of 12 years.

Excipients:

This medicine contains sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217). Parahydroxybenzoates may cause allergic reactions (possibly delayed).

This medicine contains sunset yellow (E110) and carmoisine (E122) which may cause allergic reactions.

This medicine contains maltitol (E965). Patients with rare hereditary problems of fructose intolerance should not take this medicine.

This medicine contains less than 1 mmol sodium (23mg) per 5ml, that is to say essentially “sodium free”.

The leaflet will state in “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. However, this situation only arises if excessive doses are taken (See Overdose Section). Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

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

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no reports of undesirable or damaging effects during pregnancy or to the foetus attributable to the use of this product. Nevertheless, medicines should not be used in pregnancy, especially the first trimester, unless the expected benefit is thought to outweigh any possible risk to the foetus.

Breast-feeding

Although the active ingredient is not known to be excreted in breast milk, use of this product during breast feeding is not recommended.

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 ($\geq 1/10$); common ($\geq 1/100$, $< 1/10$); uncommon ($\geq 1/1000$, $< 1/100$); rare ($\geq 1/10000$, $< 1/1000$); very rare ($< 1/10000$); not known – cannot be estimated from the available data.

Immune system disorders:

Not known: Hypersensitivity including angioneurotic oedema and skin reactions

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

* 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 the Google Play or Apple App Store.

4.9 Overdose

Symptoms: If high doses are taken diarrhoea, abdominal cramps and a clinically significant loss of potassium and other electrolytes can occur. This may also lead to increased sensitivity to cardiac glycosides.

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 in chronic overdosage are known to 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.

Management: 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

ATC code: A06AB08.

Sodium Picosulfate is a locally acting laxative from the triarylmethane group, which after bacterial cleavage in the colon, has the dual action of stimulating the mucosa of both the large intestine causing peristalsis and of the rectum causing 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.

5.2 Pharmacokinetic properties

After oral ingestion, sodium picosulfate reaches the colon without any appreciable absorption. Therefore, enterohepatic circulation is avoided. By bacterial cleavage the active form, the free diphenol, is formed in the colon. Consequently, there is an onset of action between 6 – 12 hours, which is determined by the release of the active substance from the preparation.

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

Urinary excretion reflects low systemic burden after oral administration.

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

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xanthan Gum
Methyl Hydroxybenzoate Sodium (E219)
Propyl Hydroxybenzoate Sodium (E217)

Liquid Maltitol (E965)
Sodium Saccharin
Strawberry Flavour (containing carmoisine E122, propylene glycol, isopropyl alcohol, flavouring substances, water)
Sunset Yellow (E110)
Citric Acid Anhydrous
Sodium Citrate Dihydrate
Purified Water.

6.2 Incompatibilities

None stated.

6.3 Shelf life

2 years as packaged for sale.

After first opening: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.

Keep the bottle in the outer carton.

6.5 Nature and contents of container

Pack sizes of 100 and 300ml are registered.

100ml and 300ml amber glass bottles with HDPE Child Resistant Tamper Evident Caps.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Dalkeith Laboratories Limited
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Woburn
Bedfordshire MK17 9PG.

8 MARKETING AUTHORISATION NUMBER(S)

PL 17496/0022.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/11/2007

10 DATE OF REVISION OF THE TEXT

10/03/2020