SODIUM PICOSULFATE 5MG/5ML ORAL SOLUTION

PL 17496/0022

UKPAR

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SODIUM PICOSULFATE 5MG/5ML ORAL SOLUTION

PL 17496/0022

LAY SUMMARY

The MHRA today granted Dalkeith Laboratories Limited Marketing Authorisation (licence) for the medicinal product Sodium Picosulfate 5mg/5ml Oral Solution (PL 17496/0022). This is a pharmacy only medicine (P).

Sodium Picosulfate 5mg/5ml Oral Solution belongs to a group of medicines called laxatives which are used to relieve constipation. Sodium Picosulfate 5mg/5ml Oral Solution has a dual action, stimulating the muscles of both the large intestine and rectum to bring overnight relief from constipation. Sodium Picosulfate 5mg/5ml Oral Solution may restore the sensation or desire for bowel movements so helping your body to regain its natural rhythm. The liquid is also used under medical supervision for bowel clearance before surgery or radiological investigations.

No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of taking Sodium Picosulfate outweigh the risks, hence a marketing Authorisation has been granted.
SODIUM PICOSULFATE 5MG/5ML ORAL SOLUTION

PL 17496/0022

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a marketing authorisation for the medicinal product Sodium Picosulfate 5mg/5ml Oral Solution to Dalkeith Laboratories Limited on 6th November 2007. The product is a Pharmacy only medicine.

This is submitted as abridged application according to Article 10.1 of Directive 2001/83/EC, claiming to be a generic medicinal product of the original product Laxoberal 5mg/5ml oral solution (PL06772/0011), marketed by Windsor Healthcare, granted 25 March 1993. The reference product is Laxoberal 5mg/5ml oral solution (PL00015/0249), marketed by Boehringer Ingelheim Ltd.

Sodium Picosulfate is a contact laxative used for constipation of any aetiology and bowel clearance before surgery, childbirth or radiological investigations.
PHARMACEUTICAL ASSESSMENT

DRUG SUBSTANCE

Sodium picosulfate

Structure

![Structure of Sodium Picosulfate]

Description: A white or almost white crystalline powder.

Molecular formula: \( \text{C}_{18}\text{H}_{13}\text{NNa}_{2}\text{O}_{8}\text{S}_{2}.\text{H}_{2}\text{O} \)

Molecular weight: 499.4

Synthesis of the drug substance from the designated starting material has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.

A letter of access has been supplied.

An appropriate specification based on the European Pharmacopoeia has been provided.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

All potential known impurities have been identified and characterised.

Active sodium picosulfate is stored in appropriate packaging. The specifications and typical analytical test reports are provided and are satisfactory.

Batch analysis data are provided that comply with the proposed specification.

Satisfactory certificates of analysis have been provided for working standards used by the active substance manufacturer and finished product manufacturer during validation studies.

Appropriate long-term stability data have been provided.

DRUG PRODUCT

Other ingredients

Other ingredients consist of pharmaceutical excipients, namely Xanthan Gum, Methyl Hydroxybenzoate Sodium (E219), Propyl Hydroxybenzoate Sodium (E217), Liquid
Maltitol (E965), Sodium Saccharin, Strawberry Flavour, Sunset Yellow (E110), Citric Acid Anhydrous, Sodium Citrate Dihydrate, and Purified Water.

All excipients used comply with their respective European Pharmacopoeial monograph, with the exception of Sunset Yellow (E110) and Strawberry Flavour which comply with In-house specifications.

Satisfactory specifications and Certificates of Analysis have been provided for all excipients. No materials of animal or human origin are contained in or used in the manufacture of this product.

**Manufacture**
A description and flow-chart of the manufacturing method has been provided.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation has been carried out on batches of each strength. The results are satisfactory.

**Finished product specification**
The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification. Certificates of analysis have been provided for any working standards used.

**Container Closure System**
Product is packaged in Type III glass medical bottles sealed with HDPE child resistant, tamper evident screw caps. Specifications and Certificates of Analysis for all packaging used have been provided. This is satisfactory. All primary product packaging comply with EU legislation regarding contact with solutions for parenteral and ophthalmic use Directive 2002/72/EC (as amended).

**Stability**
Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a shelf-life of 24 months with storage conditions “Protect from light” and “Do not store above 25 degree C” has been set, and this is satisfactory.

**Conclusion**
It is recommended that Marketing Authorisation is granted for this application.
PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none is required for an application of this type.
CLINICAL ASSESSMENT

INTRODUCTION
This is an abridged standard application for Marketing Authorisation in the UK submitted under Article 10.1 of Directive 2001/83/EC, ‘generic application’. The application was made on 21 June 2006.

The original product is Laxoberal 5mg/5ml oral solution (PL 06772/0011), marketed by Windsor Healthcare, granted 25 March 1993, thus the 10 year rule is fulfilled. The reference product is Laxoberal 5mg/5ml oral solution (PL 00015/0249), marketed by Boehringer Ingelheim Ltd.

BACKGROUND
Sodium Picosulfate is a contact laxative used for constipation of any aetiology and bowel clearance before surgery, childbirth or radiological investigations.

INDICATIONS
The applicant has submitted the following:
Constipation of any aetiology and bowel clearance before surgery, childbirth or radiological investigations.

Assessor’s comment
This is in line with that of the reference product.

POSOLOGY AND METHOD OF ADMINISTRATION
The applicant has submitted the following:

For oral administration.
Unless otherwise prescribed by the doctor, the following dosages are recommended:
Adults and children over 10 years:
One to two 5ml spoonfuls (5 -10mg) at night.
Children under 10 years:
Not to be taken by children under 10 years without medical advice.
Children (4-10 years):
Half to one 5ml spoonful (2.5 – 5mg) at night.
Children under 4 years:
The recommended dosage is 250 micrograms per kilogram body weight.
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.

TOXICOLOGY
No new data have been submitted and none are required.

CLINICAL PHARMACOLOGY

Pharmacodynamics
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 in creased 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.

Pharmacokinetics
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.

Bioequivalence
This is an oral solution. The excipients are not expected to modify transit or to impact on the pharmacology of the medicine. Furthermore, the active substance is not absorbed. Bioequivalence does not need to have to be assessed.

Efficacy
No new data have been submitted and none are required.

Safety
No new data have been submitted and none are required.

Clinical Overview
This clinical overview was prepared by medically qualified individual. It is satisfactory.

Summary of Product Characteristics (SPC)
The SPC is fully in line with that for the reference product.

Patient Information Leaflet
The PIL is satisfactory.

Labelling
The labelling is satisfactory.

Application Form
This conformed to EC requirements and was satisfactory.

Discussion
This is an abridged standard application for Marketing Authorisation in the UK submitted under Article 10.1 of Directive 2001/83/EC, ‘generic application’. The indication is consistent with that of the reference product.

The SPC, PIL and Labelling are fully in line with that for the reference product. A bioequivalence study is not required.
CONCLUSION
There are no medical objections to the granting of a product licence for this preparation.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The important quality characteristics of Sodium Picosulfate are well defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL
No new preclinical data were submitted and none are required for application of this type.

EFFICACY
No new data were submitted and none are required for application of this type.

The SPC, PIL and labelling are satisfactory and consistent with that for reference product.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. Extensive clinical experience with Sodium picosulfate is considered to have demonstrated the therapeutic value of the compound. The risk/benefit is, therefore, considered to be positive.
# STEPS TAKEN FOR ASSESSMENT

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<th>Description</th>
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<tr>
<td>1</td>
<td>The MHRA received the marketing authorisation application on 19th August 2005</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 28th September 2005</td>
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<td>3</td>
<td>Following assessment of the application the MHRA requested further information relating to the quality dossiers on 11th April 2006 and clinical dossier on 16th March 2007 and 31st July 2007</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 30th January 2007 and on the clinical dossier on 28th May 2007 and 16th of September 2007</td>
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<td>5</td>
<td>The application was determined on 6th November 2007</td>
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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.
For 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
Constipation of any aetiology and bowel clearance before surgery, childbirth or radiological investigations.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION
For oral administration.
Unless otherwise prescribed by the doctor, the following dosages are recommended:
Adults and children over 10 years:
One to two 5ml spoonfuls (5 -10mg) at night.
Children under 10 years:
Not to be taken by children under 10 years without medical advice.
Children (4-10 years):
Half to one 5ml spoonful (2.5 – 5mg) at night.
Children under 4 years:
The recommended dosage is 250 micrograms per kilogram body weight.
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.

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 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 long periods. Patients who need to take laxatives frequently should do so under medical supervision only and should have the cause of their constipation investigated.
Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalaemia, and may precipitate onset of rebound constipation.
Not to 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. However, this situation only arises if excessive doses are taken (See Overdose Section). Concurrent administration of broad spectrum antibiotics may reduce the laxative action of this product.

4.6 PREGNANCY AND LACTATION
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. 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
None stated.

4.8 UNDESIRABLE EFFECTS
Abdominal discomfort (including abdominal pain and cramps) and diarrhoea may occasionally occur. Isolated cases of allergic reactions (including skin reactions and angio-oedema) have been reported rarely in association with the administration of sodium picosulfate.

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. 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
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.

6.4 SPECIAL PRECAUTIONS FOR STORAGE
Do not store above 25°C.
Keep container in 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
2 Park Street
Woburn
Bedfordshire MK17 9PG.

8 MARKETING AUTHORISATION NUMBER(S)
PL 17496/0022.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
10 DATE OF REVISION OF THE TEXT
August 2007.
Sodium Picosulfate Sng/Sml Oral Solution

What You Should Know About Sodium Picosulfate Sng/Sml Oral Solution

Please read this leaflet carefully before you start using this medicine. This is the summary of information about the medicine from the manufacturer. It is intended for healthcare professionals. It does not take into account your specific medical condition or other factors. It is not a substitute for professional medical advice, diagnosis or treatment. Always ask your doctor or pharmacist for advice if you have any concerns about using this medicine.

Each pack of Sodium Picosulfate Sng/Sml Oral Solution contains 50g of Sodium Picosulfate as monohydrate in the active ingredient. The sodium concentration is 5mg/mL.

The active ingredient in the medicine is Sodium Picosulfate. This is the name for Sodium Picosulfate. The ingredient itself has not changed.

In the event of overdose, consult a doctor immediately.

Before Taking Sodium Picosulfate Sng/Sml Oral Solution

Do not take this medicine if:
- You suffer from any of the following: high blood pressure, kidney or heart disease, diabetes, multiple sclerosis, peptic ulcer, stomach, or intestine problems, diarrhoea, or if you have any of the other ingredients in Sodium Picosulfate Sng/Sml Oral Solution.
- You are allergic to Any of the ingredients in this medicine.
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LABELLING

Oral Solution

Dosage: Adults and children over 10 years: One to two 5ml spoonfuls at night or as directed by your doctor. Children under 10 years of age: consult your doctor.

CAUTION: If laxatives are needed every day or if you have persistent abdominal pain consult your doctor. Please see leaflet for further information.

Do not store above 25°C.

Keep container in outer carton.

Keep out of the sight and reach of children.

Do not use if seal on bottle is broken.

Ingredients: Each 5ml contains 5mg of Sodium Picosulfate (as Monohydrate). Also contains: Xanthan Gum, Methyl Hydroxybenzoate Sodium, Propyl Hydroxybenzoate Sodium, Liquid Maltitol, Sodium Saccharin, Strawberry Flavour (contains Carmine E122, Propylene glycol, Isopropyl alcohol, flavouring substances and water), Sunset Yellow E110, Citric Acid Anhydrous, Sodium Chloride Dihydrate, Purified Water.

P 3145

BN: PL 17496/0022

MA Holder: Dalkath Laboratories Ltd, 2 Park Street, Woburn, Bedfordshire MK17 9PG, United Kingdom