Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution

PL 20416/0283

UKPAR

TABLE OF CONTENTS

Lay Summary .......................... Page 2
Scientific Discussion ................. Page 4
Steps Taken for Assessment ........ Page 11
Steps Taken After Initial Authorisation Page 12
Summary of Product Characteristics Page 13
Patient Information Leaflet .......... Page 14
Labelling .............................. Page 15
LAY SUMMARY

This is a summary of the public assessment report (PAR) for Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution (PL 20416/0283). It explains how Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution.

For practical information about using Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution, patients should read the package leaflet or contact their doctor or pharmacist.

**What is Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution and what is it used for?**
This medicine is the same as OTC Concepts Liquid Laxative 5mg/5ml Oral Solution, which is already authorised to OTC Concepts Limited. OTC Concepts Limited has agreed that this Marketing Authorisation can be used as a basis for the grant of an identical Marketing Authorisation (informed consent).

This medicine is used for the short-term relief of constipation. It has a dual action, stimulating the muscles of both the large intestine and rectum to bring overnight relief from constipation. It may restore the sensation or desire for bowel movements so helping the body to regain its natural rhythm.

**How does Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution work?**
This oral solution contains the active ingredient sodium picosulfate. Sodium picosulfate belongs to a group of medicines called laxatives and works by making bowel muscles contract more often and with more force. This increased muscle action moves bowel contents to the rectum to be emptied and relieves constipation. This medicine takes about 6-12 hours to have an effect.

**How is Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution used?**
Adults and children over 10 years should take 5-10 mg (one to two 5 ml spoonfuls) at night. Once bowel movements have returned to normal this medicine should be stopped. This medicine should not be used for more than 5 days; if constipation continues after this, patients should see their doctor.

Children under 10 years should not take this medicine unless prescribed by a doctor.

This medicine can be obtained without a prescription.
What benefits of Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution have been shown in studies?
Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution is considered to be identical to previously authorised medicinal product, with the same benefits and risks. Therefore, no new studies have been provided but reference is made to the Marketing Authorisation owned by OTC Concepts Limited.

What are the possible side effects from Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution?
Like all medicines Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution can cause side effects, although not everybody gets them. The most common side effect reported, which may affect more than 1 in 10 people, is diarrhoea.

For the full list of all side effects reported with Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution, see section 4 of the package leaflet. For the full list of restrictions, see the package leaflet.

Why is Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution approved?
The MHRA decided that the benefits of Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution?
A Risk Management Plan has been developed to ensure Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution is used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics and the package leaflet for Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored and reviewed continuously.

Other information about Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution
A Marketing Authorisation was granted in the UK on 29 July 2015.

This summary was last updated in September 2015.

The full PAR for Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution follows this summary.
CRESCENT PHARMA LIQUID LAXATIVE 5MG/5ML ORAL SOLUTION

PL 20416/0283

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Introduction</th>
<th>Page 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical Assessment</td>
<td>Page 6</td>
</tr>
<tr>
<td>Non-clinical Assessment</td>
<td>Page 8</td>
</tr>
<tr>
<td>Clinical Assessment</td>
<td>Page 9</td>
</tr>
<tr>
<td>Overall Conclusion and Benefit/Risk Assessment</td>
<td>Page 10</td>
</tr>
</tbody>
</table>
INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Crescent Pharma Limited a Marketing Authorisation for the medicinal product Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution (PL 20416/0283) on 29 July 2015. This is a General Sales List medicine.

Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution is indicated for the short term relief of constipation.

This application was submitted as an abridged application, according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to the Marketing Authorisation for OTC Concepts Liquid Laxative 5mg/5ml Oral Solution (PL 20338/0019), which is already authorised to OTC Concepts Limited.

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.

No new data were submitted nor were necessary for this simple application, as the data are identical to those provided for the previously authorised product.
1. INTRODUCTION
This is an abridged application for Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution, submitted under Article 10c of Directive 2001/83/EC, as amended.

The application cross-refers to OTC Concepts Liquid Laxative 5mg/5ml Oral Solution (PL 20338/0019) which was authorised to OTC Concepts Limited on 8 November 2010. OTC Concepts Liquid Laxative 5mg/5ml Oral Solution is a duplicate of Sodium Picosulfate 5mg/5ml Oral Solution (PL 17496/0022) which was authorised to Dalkeith Laboratories Limited on 6 November 2007 and cross refers to Laxoberal Liquid (PL 00015/0249) which was originally authorised to Windsor Healthcare Limited on 25 March 1993 (PL 06772/0011).

The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 Name
The name of the product is acceptable.

2.2 Strength, pharmaceutical form, route of administration, container and pack size
The solution has the same strength, form and route of administration as the reference product.

The solution is stored in 60 ml amber glass bottles with HDPE child resistant tamper evident caps.

Product stored in unopened bottles has a shelf life of 2 years. Once the bottle is first opened the product shelf life is 1 month.

2.3 Legal status
This is a General Sales List (GSL) medicine.

2.4 Marketing Authorisation Holder
The Marketing Authorisation Holder is Crescent Pharma Limited, Units 3 & 4, Quidhampton Business Units, Polhampton Lane, Overton, Hants RG25 3ED, UK.

The Qualified Person (QP) responsible for pharmacovigilance is stated and a satisfactory CV has been provided.

2.5 Manufacturers
The manufacturing sites are identical to those of the reference product and are acceptable.
2.6 Qualitative and quantitative composition
The product composition is identical to that of the reference product and is acceptable.

2.7 Manufacturing process
The manufacturing process is identical to that of the reference product and is acceptable.

2.8 Finished product/shelf-life specification
The finished product specification is identical to that of the reference product and is acceptable.

2.9 Drug substance specification
The drug substance specification is identical to that of the reference product and is acceptable.

2.10 TSE Compliance
None of the excipients contain materials of animal or human origin.

2.11 Bioequivalence
No bioequivalence data are required to support this simple abridged application because the product is identical to a product that is already authorised.

3. EXPERT REPORTS
These are acceptable.

4. PRODUCT NAME AND APPEARANCE
The name of the product is acceptable. The appearance of the solution is in line with the reference product and is acceptable.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The Summary of Product Characteristics is identical to that of the reference product, apart from the necessary administrative updates to reflect the change in Marketing Authorisation, and is acceptable.

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING
The PIL and label are identical to those of the reference product, apart from the necessary administrative updates to reflect the change in Marketing Authorisation, and are acceptable.

7. CONCLUSION
The data submitted with the application are acceptable. The grant of a Marketing Authorisation is recommended.
NON-CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA).

The grant of a Marketing Authorisation is recommended.
CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided details of a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that they have the services of a qualified person responsible for pharmacovigilance, and have the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

The Risk Management Plan is considered adequate. Routine risk minimisation is provided through the Summary of Product Characteristics and the Patient Information Leaflet and this is sufficient.

The grant of a Marketing Authorisation is recommended.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY
The data for this application are consistent with the data previously assessed for the Marketing Authorisation for OTC Concepts Liquid Laxative 5mg/5ml Oral Solution (PL 20338/0019) and, as such, have been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for this type of application.

EFFICACY
The product is identical to that previously authorised; therefore, no efficacy data are needed.

SAFETY
No new or unexpected safety concerns arose from this application.

PRODUCT LITERATURE
The SmPC, PIL and label are identical to those previously approved, apart from the necessary administrative updates to reflect the change in Marketing Authorisation.

BENEFIT/RISK ASSESSMENT
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the reference product. The benefit/risk balance is therefore considered to be positive.
### STEPS TAKEN FOR ASSESSMENT

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The MHRA received the Marketing Authorisation Application on 19 November 2014.</td>
</tr>
<tr>
<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 18 December 2014.</td>
</tr>
<tr>
<td>3</td>
<td>Following assessment of the application the MHRA requested further information relating to the dossier on 18 March 2015.</td>
</tr>
<tr>
<td>4</td>
<td>The applicant responded to the MHRA’s request, providing further information on 1 June 2015.</td>
</tr>
<tr>
<td>5</td>
<td>The application was granted on 29 July 2015.</td>
</tr>
</tbody>
</table>
## STEPS TAKEN AFTER INITIAL AUTHORISATION

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
PATIENT INFORMATION LEAFLET

In accordance with Directive 2010/84/EU, the Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
LABELLING

The following text is the approved label text for Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution. This label text is identical to those for the other medicinal products, with the exception of differences in the product names and strengths. No label mock-ups have been provided. In accordance with medicines legislation, the products shall not be marketed in the UK until approval of the label mock-ups has been obtained.
PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 5ml of oral solution contains 5mg of Sodium Picosulfate (as monohydrate)

3. LIST OF EXCIPIENTS

Also contains methylhydroxybenzoate sodium (E219), propylhydroxybenzoate sodium (E217), liquid maltitol (E965), carmoisine (E122) and sunset yellow (E110).

4. PHARMACEUTICAL FORM AND CONTENTS

60 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Please read the leaflet provided before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep the container in outer carton. Discard 28 days after opening. Do not use if seal on bottle is broken.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE
11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Crescent Pharma Ltd.
Polhampton Lane, Overton.
Hampshire, RG25 3ED, UK.

12. MARKETING AUTHORISATION NUMBER(S)

PL 20416/0283

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

GSL

15. INSTRUCTIONS ON USE

Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution is a fruit flavoured liquid with a dual action to bring gentle overnight relief from constipation and it may also help the bowel to return to normal regular function.

Dose:
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.

Consult your doctor if:
- laxatives are needed every day
- you have persistent abdominal pain
- you remain constipated after taking this medicine for 5 days

16. INFORMATION IN BRAILLE

Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

BOTTLE

1. NAME OF THE MEDICINAL PRODUCT

Crescent Pharma Liquid Laxative 5mg/5ml Oral Solution

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 5ml of oral solution contains 5mg of Sodium Picosulfate (as monohydrate).

3. LIST OF EXCIPIENTS

Also contains methylhydroxybenzoate sodium (E219), propylhydroxybenzoate sodium (E217), liquid maltitol (E965), carmoisine (E122) and sunset yellow (E110).

4. PHARMACEUTICAL FORM AND CONTENTS

60 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Please read the leaflet provided before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep the container in outer carton. Discard 28 days after opening.
Do not use if seal on bottle is broken.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE
11. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Crescent Pharma Ltd,
Polhampton Lane, Overton,
Hampshire, RG25 3ED, UK.

12. **MARKETING AUTHORISATION NUMBER(S)**

PL 20416/0283

13. **BATCH NUMBER**

BN

14. **GENERAL CLASSIFICATION FOR SUPPLY**

GSL

15. **INSTRUCTIONS ON USE**

Dose:
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.

16. **INFORMATION IN BRAILLE**