UK Public Assessment Report

Senna 7.5 mg Tablets

PL 13931/0032

Chanelle Medical
Lay Summary
Senna 7.5 mg Tablets
(Senna leaf; Cassia senna L. (C. acutifolia Delile) or Cassia angustifolia Vahl)

This is a summary of the Public Assessment Report (PAR) for Senna 7.5 mg Tablets (PL 13931/0032). It explains how Senna 7.5 mg Tablets were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use Senna 7.5 mg Tablets.

For practical information about using Senna 7.5 mg Tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Senna 7.5 mg Tablets and what are they used for?
Senna 7.5 mg Tablets are a ‘generic medicine’. This means that they are similar to a ‘reference medicine’, already authorised in the European Union (EU) called Senokot Tablets.

Senna 7.5 mg Tablets are used for the short term relief of occasional constipation.

How do Senna 7.5 mg Tablets work?
Senna 7.5 mg Tablets contain the active substance Senna leaf (Cassia senna L. (C. acutifolia Delile) or Cassia angustifolia Vahl). A component of Senna leaf, Sennoside B, has a laxative effect producing increased movement of the bowels.

How are Senna 7.5 mg Tablets used?
Senna 7.5 mg Tablets should be swallowed whole with water.

Please read Section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration and the duration of treatment.

In adults, the elderly and children over the age of 12 years the recommended dose is two tablets at night. The product is not recommended for use in children under 12 years.

Medical supervision should be sought if use of this product is required for more than 1 to 2 weeks.

This medicine can be obtained without a prescription.

What benefits of Senna 7.5 mg Tablets have been shown in studies?
Senna 7.5 mg Tablets are considered to be comparable to the reference medicine, Senokot Tablets. Senna 7.5 mg Tablets are expected to be processed by the body in the same way as Senokot Tablets and, therefore, no further studies were considered necessary.

What are the possible side effects of Senna 7.5 mg Tablets?
Because Senna 7.5 mg Tablets are a generic medicine, their benefits and possible side effects are taken as being the same as those of the reference medicine, Senokot Tablets.

For further information, please see the package leaflet.

Why are Senna 7.5 mg Tablets approved?
It was concluded that, in accordance with EU requirements, Senna 7.5 mg Tablets have been shown to have comparable quality and be comparable to Senokot Tablets. Therefore, the
view was that, as for Senokot Tablets, the benefits outweigh the identified risks and Senna 7.5 mg Tablets can be approved for use.

**What measures are being taken to ensure the safe and effective use of Senna 7.5 mg Tablets?**
Known side effects are continuously monitored. Furthermore new safety signals reported by patients and healthcare professionals will be monitored and reviewed continuously as well.

**Other information about Senna 7.5 mg Tablets**
A marketing authorisation in the UK was granted to the Marketing Authorisation holder, Chanelle Medical, on 21 February 2007.

The full PAR for Senna 7.5 mg Tablets follows this summary.

For more information about treatment with Senna 7.5 mg Tablets, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in June 2015.
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I Introduction

Based on the review of the data on quality, safety and efficacy, the UK granted a marketing authorisation (MA) for the medicinal product Senna 7.5 mg Tablets.

This product is a General Sales List (GSL) medicine, indicated for the short term relief of occasional constipation.

This application was made under Article 10(1) of Directive 2001/83/EC, as amended, claiming to be a generic medicinal product. The reference medicinal product, which has been authorised in accordance with Community provisions in force for not less than 10 years in the European Economic Area (EEA), is Senokot Tablets (PL 00063/5000R). This product was granted a Product Licence of Right to Westminster Laboratories Limited in 1972. Following a change in company name, Senokot Tablets have been authorised in the UK, to Reckitt Benckiser Healthcare (UK) Limited since 13 March 1987.

Senna 7.5 mg Tablets contain the active pharmaceutical ingredient senna leaf, equivalent to a total sennoside content (calculated as sennoside B) of 7.5mg. Senna leaf is a stimulant laxative which stimulates peristalsis in the intestine.

A licence was granted in the UK to Chanelle Medical on 21 February 2007.
II Quality aspects

II.1 Introduction
The application is submitted according to Article 10(1) of Directive 2001/83/EC, as amended. The applicant has specified Senokot Tablets (PL 00063/5000R) as the EU reference medicinal product (MA Holder: Reckitt Benckiser Healthcare (UK) Limited).

Senna 7.5 mg Tablets are formulated as greenish-brown biconvex tablets.

Each tablet contains 203 mg of the active pharmaceutical ingredient Senna Leaf (Cassia senna L. (C. acutifolia Delile) or Cassia angustifolia Vahl), corresponding to a total sennoside content (calculated as sennoside B) of 7.5 mg. The excipients present in the tablet are: maize starch, croscarmellose sodium and magnesium stearate.

The tablets are presented in a propylene container with a polyethylene tamper evident wadless closure, in pack sizes of 20, 50, 60, 100, 200 500 and 1000 tablets.

II.2 Drug Substance

Senna Leaf
Powdered senna leaf is purchased from a suitable supplier.

An appropriate specification based on the European Pharmacopoeia monograph is provided for senna leaf.

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

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

Senna leaf is stored in appropriate packaging.

Senna leaf is retested prior to use in the drug product.

II.3 Medicinal Product

Other ingredients
All excipients used in the manufacture of the tablets are routinely tested for compliance with current relevant international standards.

Satisfactory certificates of analysis have been provided for all excipients.

None of the excipients used contain material of animal or human origin.

Manufacture of the product
A full description and a detailed flow-chart of the manufacturing method including in-process control steps has been provided.

In-process controls are appropriate considering the nature of the product and the method of manufacture. The results of the process validation are satisfactory.
Product Specifications
The proposed finished product specification is acceptable and the analytical methods used have been suitably validated. Batch analysis data have demonstrated compliance with the proposed release specification.

Container Closure System
Satisfactory specifications and certificates of analysis have been provided for the packaging components.

Stability of the product
Finished product stability data support the proposed shelf-life of 36 months with no special storage conditions.

Bioequivalence/bioavailability
A bioequivalence study was not required for this application as the drug product is locally acting.

SmPC, PIL and Labels
The SmPC, PIL and labels are pharmaceutically acceptable.

II.4 Discussion on chemical, pharmaceutical and biological aspects
The applicant’s product has the same qualitative and quantitative composition in terms of active principles, and the pharmaceutical form is the same, therefore, Senna 7.5 mg tablets are considered to be a generic product of Senokot Tablets.

It is recommended that a Marketing Autorisation should be granted for this application.

III Non-clinical aspects
No new non-clinical data have been supplied with the application and none are required for an application of this type.

IV Clinical aspects
Introduction
Senna, the active ingredient of these tablets, is an anthraquinone stimulant laxative used to treat constipation. The content is calculated, both in Europe and the US, as sennoside B. It has been in clinical use world-wide for many years.

Background
Chanelle Medical have submitted a licence application for tablets containing 7.5 mg senna, in accordance with article 10.1 of Directive 2001/83/EC as amended, referring to the original product Senokot Tablets. The present application relies on the extensive literature available on senna.

Indications
The proposed indication is for the relief of occasional or non-persistent constipation. These are considered to be satisfactory and are fully consistent with the SmPC for Senokot Tablets.
Dose and dose schedule
The usual dose for adults, including the elderly and children over 12 years of age is two tablets taken at night.

Toxicology
No data are presented and none are required for this application.

Clinical Pharmacology
No data are presented and none are required for this application.

Clinical efficacy
No new efficacy data are presented and none are required for this application.

Clinical safety
No new data are presented and none are required for this application. The adverse events that can be expected are listed in the Summary of Product Characteristics.

Risk Management Plan (RMP)
No Risk Management Plan was submitted and none was required; this application was received prior to 21 July 2012, the date from which pharmacovigilance regulations, in accordance with Directive 2010/84/EU, came into force.

Expert Reports
There is a satisfactory clinical expert report, including relevant references up to the year 2000, written by an appropriately qualified medical doctor.

SmPC, PIL and labels
The SPC, PIL and labels are acceptable.

Discussion on the clinical aspects
Overall, there is no clinical objection to grant a Marketing Authorisation for this application. No new or unexpected safety concerns arose from the application. Senna, in the form of Sennoside B, has been in clinical use world-wide for many years. The SPC, PIL and labelling are satisfactory and are consistent with those for the reference product.

V  User consultation
This application was submitted before 01 July 2005 and, therefore, preceded the UK requirement for user consultation with target patient groups on the package leaflet for a new marketing authorisation.

VI  Overall conclusion, benefit/risk assessment and recommendation

Quality
The important quality characteristics of Senna 7.5mg Tablets 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.

**Non-clinical**
No new non-clinical data were submitted and none are required for an application of this type.

**Efficacy**
No new or unexpected safety concerns arise from this application.

The SmPC, PIL and labels are satisfactory and consistent with that for the reference product.

**Risk benefit assessment**
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. Clinical experience with senna leaf is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory, in line with current guidelines and consistent with the reference product. In accordance with Directive 2012/84/EU, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

The currently approved labelling texts are listed below:

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**Senna 7.5 mg Tablets**

60 Tablets

Tablets for oral use.
Each tablet contains senna equivalent to 7.5 mg total sennosides.

Please read enclosed leaflet carefully before use.

**Directions for Use:**
Adults and children over 12: Take 2 Tablets at night. Do not exceed stated dose.
Children aged between 6 – 12 years: Consult your doctor.
Do not give to children under 6 years of age.

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To: PL 13931/0032
To: Marketing Authorisation Holder: Chatelle Medical Ireland
UKPAR Senna 7.5 mg Tablets

PATIENT INFORMATION LEAFLET
SENNA 7.5 MG TABLETS

Please read this leaflet carefully before you take this medicine. Keep this leaflet you may need to read it again. If you find that you still have questions or are unsure about anything, ask your doctor or pharmacist.

What is in your medicine?
Each Senna 7.5 mg Tablet contains the following ingredients:
Senna 7.5 mg Tablets are available in packs of 20, 50, 60, 100, 200, 500 and 1000 Tablets.
The Product Licence Holder and manufacturer is: Channell Medical, Loughrea, Co. Galway, Ireland.

UK Distributor: Channell Medical U.K. Ltd., Obased Bore, Smarden, Kent TN27 8PR, UK.

What is Senna?
In the raw state senna contains a variable quantity of the active ingredient (sesquiterpenes). However, the sesquiterpene content of the senna used in the manufacture of Senna 7.5 mg Tablets is standardised to ensure that you receive a constant amount of active ingredient and a predictable result from every dose.

What is your medicine for?
Constipation is a fairly common and uncomfortable complaint. It usually involves difficult or irregular bowel movements, accompanied by hard, dry motions, which can be painful to pass.
Senna works by gently stimulating the bowel to encourage bowel movement for the relief of occasional or non-permanent constipation.
People’s toilet routines and bowel habits tend to differ; for some, once a day is normal, whilst others may feel comfortable going three times a week. If your normal routine changes and you experience abdominal discomfort or a bloated feeling, it might be constipation.

There may be many causes of constipation. It might be brought on by an unhealthy diet, especially one without enough fibre. It could be due to changes in lifestyle, often related to today’s hectic pace of life. It can also be caused by illness or a reaction to medicines taken.
So, whenever you feel constipated, for whatever reason, Senna 7.5 mg Tablets provide gentle and predictable relief.

What do you need to know before taking this medicine?
As with all medicines, Senna 7.5 mg Tablets may not be suitable for some people.
If you have sharp or persistent stomach pain, or if your doctor has warned you to stop taking a medicine during the last 24 hours, consult your doctor.

How should you take your medicine?
Adults and children over the age of 12 should take two tablets at night. Senna 7.5 mg Tablets usually act within 8-10 hours.
For children aged 6 to 12 years, your doctor should be consulted before Senna 7.5 mg Tablets are taken.
The product is not recommended for use in children under 6 years.
The tablets should be taken with a glass of water.
Unless your doctor has given you different instructions on how many Senna 7.5 mg Tablets to take, follow the advice given in this leaflet.
Make sure you do not exceed more than two tablets in any 24-hour period.

If you need to take Senna 7.5 mg Tablets every day, or abdominal pain persists, consult your doctor.
If you do not have a bowel movement after three days, consult your doctor.

What side-effects can occur with this medicine?
You may experience temporary mild stomach pains when changing dosage.
If you have any other symptoms after taking this product, tell your doctor or pharmacist.

What if you take too much of your medicine?
If you accidentally take too many Senna 7.5 mg Tablets, consult your doctor or pharmacist for advice.

How should you store your medicine?
The expiry date is stated on the label. Do not take the medicine after this date.
Keep Senna 7.5 mg Tablets out of the reach and sight of children.

Leaflet last revised Aug 2005

1000 Tablets
Senna 7.5 mg Tablets
A tablet contains the following natural senna, to give predictable constipation relief

Tamsulosin HCl Tablets 0.4 mg, Senna 7.5 mg Tablets are a medicine for the treatment of constipation, to give predictable constipation relief.

Directions for Use:
Adults and children over 12 years:
Take 2 tablets at night (Do not take more than 2 tablets at any time).
Consult your doctor if symptoms persist.

Children aged 6 to 12 years:
Consult your doctor before use.

Do not use in children under 6 years of age.
Senna 7.5 mg Tablets usually act within 6-10 hours.

Do not exceed the number of tablets stated on the packaging.
Store out of the reach and sight of children.

Marketing Authorisation Holder:
Channell Medical, Loughrea, Co. Galway, Ireland
PL 1393/0032

Warnings:
If you have mild or persistent pains, consult your doctor after use.
Do not exceed the stated dose.
Distributed by:
Channell Medical U.K. Ltd.
UKPAR Senna 7.5 mg Tablets

PL 13931/0032

Directions for use:
- Adults and children over 12: Take 1 tablet at night.

Tablets for oral use.
Each tablet contains senna equivalent to 7.5 mg total anthraquinones.

Warnings:
- If symptoms or abdominal pain persist consult your doctor. Store out of the reach of children.
- Do not take more than 2 tablets in any 14 day period.
- Children aged between 6 - 12 years
- Consult your doctor.
- Do not give to children under 6 years of age.
- Senna 7.5 mg tablets usually acts within 8 - 12 hours. Dosage can be repeated on a daily basis until bowel action is restored, but if there is no bowel movement within 3 days of use, consult your doctor.
- Please read and use exact label carefully before use.
# Table of content of the PAR update for MRP and DCP

Steps taken after the initial procedure with an influence on the Public Assessment Report (Type II variations, PSURs, commitments)

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<td>17 December 2014</td>
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<td>To update SmPC to introduce a clear warning regarding long-term use of laxatives. Additionally, the remainder of the SmPC has been updated in line with the HMPC European Community monograph for Senna Leaf.</td>
<td>Granted 08 May 2015</td>
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Annex I

Reference: PL 13931/0032 - 0018
Product: Senna 7.5 mg Tablets
Marketing Authorisation Holder: Chanelle Medical
Active Ingredients: Senna Leaf

Reason:
To update SmPC section 4.4 (special warnings) to introduce a clear warning regarding long-term use of laxatives. Additionally, the remainder of the SmPC has been updated in line with the HMPC European Community monograph for Senna Leaf. As a consequence, text versions of the label and leaflet have been submitted and updated accordingly. A PIQ submission will be submitted to assess the mock ups.

Supporting Evidence
An updated SmPC, labelling and package leaflet has been updated.

Evaluation
In addition to the product information updates for stimulant laxatives requested by VRMM, the applicant was requested to update the product information submitted (SmPC, package leaflet and labelling) in line with the HMPC European Community monograph for Senna Leaf.

Additionally, the applicant was asked to update Section 2 of the SmPC in line with the ‘Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products’.

The SmPC, label text and leaflet text have been updated to include the stimulant laxative warnings and are now in line with the HMPC European Community monograph for Senna Leaf.

The applicant has been advised that mock-ups of proposed the labelling and leaflet, including suitable user test data (where needed), should be submitted to the Patient Information Quality Unit for assessment prior to marketing. Any extra-statutory information included on labelling components (straplines) has not been assessed with this submission and will be subject to formal assessment by the Patient Information Quality Unit as part of the submission of mock-ups prior to marketing.

The current approved UK versions of the SmPC and PIL for this product are available on the MHRA website. The approved labelling following this update is presented below.

Decision - Granted
Date - 08 May 2015
PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

1. NAME OF THE MEDICINAL PRODUCT

Senna 7.5 mg Tablets
Senna Leaf

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 203mg of Senna leaf (Cassia senna L. (C. acutifolia Delile) or Cassia angustifolia Vahl) corresponding to 7.5 mg hydroxyanthracene glycosides, calculated as sennoside B.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

1000 tablets
500 tablets
200 tablets
100 tablets
60 tablets
50 tablets
20 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use only.
Adults, the elderly and children over 12: Take 2 tablets at night.

Read enclosed package leaflet 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

Do not exceed stated dose

If there is no bowel movement after 3 days, consult your doctor

Use for more than 1-2 weeks requires medical supervision
If symptoms or abdominal pain worsen, or persist consult your doctor.
Do not take if:
- You have bowel or stomach problems
- You have had an allergic reaction to any of the ingredients
- You are pregnant or breastfeeding
- You have a heart or condition or kidney disorder
- You are under 12 years old

8. EXPIRY DATE

Expiry Date:

9. SPECIAL STORAGE CONDITIONS

Store in the original container

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

Chanelle Medical, Loughrea, Co. Galway, Ireland.
Distributed by: Chanelle Medical U.K. Ltd

12. MARKETING AUTHORISATION NUMBER (S)

PL 13931/0032

13. BATCH NUMBER

Batch No.: 

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription

15. INSTRUCTIONS ON USE

16. Other

Used for the short-term relief of occasional constipation.

Laxatives do not affect the number of calories absorbed from food.

This means they do not help with weight loss.
Senna 7.5 mg tablets usually acts within 8 – 12 hours. If there is no bowel movement within 3 days of use, consult your doctor.

17. INFORMATION IN BRAILLE

Senna 7.5 mg Tablets