IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0030/055/001
Case No: 2067774

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Novartis Consumer Health UK Ltd

Wimblehurst Road, **Horsham**, **West Sussex RH12 5AB**, **England**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Ex-Lax Senna Pills 12mg Sugar Coated Tablets

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **22/06/2009** until **21/04/2012**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ex-Lax Senna Pills 12mg Sugar Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20mg standardised senna dry extract equivalent to 12mg sennosides calculated as sennosides A & B.

For excipients see section 6.1

3 PHARMACEUTICAL FORM

Sugar coated tablets.

Circular, biconvex, brownish red sugar coated tablets with approximately 6mm diameter.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Relief of occasional constipation

4.2 Posology and method of administration

The following doses are normally taken at bedtime

Adults and children over 12: 1 tablet

A second dose may be taken during the day if required. Do not exceed two doses in any 24 hours.

Not recommended for children under 12.

There is no indication that the dosage should be modified for the elderly.

Route:
Oral route of administration.

4.3 Contraindications

Ex-Lax Senna Pills should not be given to patients with symptoms of appendicitis, intestinal obstruction bleeding, inflammatory bowel disease, including ulcerative colitis or abdominal pain of unknown origin
Not recommended in cases of ileostomy or colostomy.

4.4 Special warnings and precautions for use

Prolonged use is not recommended. Ex-Lax Senna Pills should not be used for more than 7 days without seeking medical advice.

Label/leaflet precaution:
If a laxative is needed every day or there is persistent abdominal pain - consult your doctor.
If there is no bowel movement after 3 days consult your doctor.

Ex-Lax Senna Pills should be used with caution shortly after bowel surgery.

During use of Ex-Lax Senna Pills, an adequate level of fluid intake should be maintained.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

Ex-Lax Senna should not be used during pregnancy and lactation unless considered essential by the physician. Anthroquinones are excreted in breast milk but clinical studies have shown that the breast fed infants of mothers taking a senna laxative did not show any side effects to the drug.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Temporary mild griping may occur.

4.9 Overdose

Overdosage may result in diarrhoea with excessive loss of water and electrolytes, particularly potassium. Treatment should include an increase in fluid intake to reverse the loss of fluid and electrolytes.

Prolonged, excessive use of laxatives without interruption should be avoided because of the risk of electrolyte imbalances and in extreme cases the possibility of irreversible adverse effects on the bowel.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Senna is an anthraquinone laxative which is used to treat constipation and for bowel evacuation before radiological procedures. The active anthraquinones are liberated into the colon from glycosides by colonic bacteria and an effect usually occurs 6 to 12 hours after administration.

5.2 Pharmacokinetic properties

There is some absorption of the anthraquinones from senna preparations following hydrolysis by colonic bacteria. Excretion occurs in the urine and faeces and also in other secretions including milk.
(Although anthraquinone derivatives may be excreted in the milk of lactating mothers, following normal dosage the concentration is usually insufficient to affect the nursing infant).

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Lactose monohydrate,
Maize starch,
Talc,
Acacia,
Titanium dioxide (E171),
Glucose,
Stearic acid,
Gelatin,
Colloidal anhydrous silica,
Red iron oxide (E172),
Carnauba wax.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Transparent or blue coloured blister pack composed of PVC/PVdC blisters sealed with aluminium foil.

Pack sizes: 6, 9, 10, 12, 18, 20, 24, 30, 36 or 48 tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Novartis Consumer Health UK Ltd.,
Trading as: Novartis Consumer Health,
Wimblehurst Road,
Horsham,
West Sussex,
RH12 5AB,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER

PA30/55/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation 13th April 2007.

10 DATE OF REVISION OF THE TEXT