IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA1161/007/001
Case No: 2046426

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

Transferred from PA0100/027/002.

Chemidex Pharma Limited

Chemidex House, **Egham Business Village**, **Crabtree Road, Egham**, **Surrey TW20 8RB**, **United Kingdom**

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

Fletchers' Phosphate Enema

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 **28/03/2008** until **22/06/2008**.

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

Fletchers' Phosphate Enema

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The solution contains:

Sodium Dihydrogen Phosphate Dihydrate	10	% w/v
Disodium Phosphate Dodecahydrate	8	% w/v

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Rectal solution.

A clear, colourless liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For evacuation of the colon in constipation, prior to surgical and diagnostic procedures and in obstetrics prior to delivery.

4.2 Posology and method of administration

For rectal use only.
Adults: The usual dose is one enema as required.
Children (over 3 years): In proportion according to body weight.
Children (under 3 years): Not recommended.

4.3 Contraindications

1. Use in patients with inflammatory or ulcerative conditions of the large bowel, or in those with increased colonic absorptive capacity.
2. Use in patients with acute gastro-intestinal conditions.

4.4 Special warnings and precautions for use

1. Prolonged use may lead to irritation of the anal canal.
2. This product should be used with great caution in patients requiring a reduced sodium intake, and electrolyte balance should be maintained during extended use.
3. There have been occasional reports of vasovagal attacks occurring in elderly patients following the administration of phosphate enema.

Care should be taken not to use undue force in administration of the enema especially in elderly or debilitated patients or those with neurological disorders.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Pregnancy and lactation

No special warnings

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

There have been occasional reports of apparent vasovagal attacks occurring in elderly patients following administration of phosphate enema.

4.9 Overdose

There have been no cases of overdose. In the event of overdosages, electrolyte levels should be monitored and balance restored where appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The active ingredients of Fletchers' Phosphate Enema are sodium dihydrogen phosphate dihydrate and disodium phosphate dodecahydrate, both of which are laxatives. These active ingredients exert their laxative effects upon the lower intestine via their osmotic properties following rectal administration.

5.2 Pharmacokinetic properties

Saline laxatives are poorly and slowly absorbed from the intestine following rectal administration. Since Fletchers' Phosphate Enema is presented as a single dose enema for rectal administration, only minimal absorption is likely to occur.

5.3 Preclinical safety data

There are no preclinical 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

Benzalkonium Chloride
Disodium Edetate
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

PVC Bag: 1 year
LDPE Bottle: 3 years

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

1. Neutral, translucent, plasticised PVC enema bags with PVC nozzle, the long tube form has a welded tube between the bag and nozzle. Individually packed in a sealed polypropylene bag. Pack size: 128 ml.
2. An LDPE bottle with a PVC or LDPE nozzle, rubber non-return valve, and plastic overcap. The nozzle to be lubricated with White Soft Paraffin BP. Individually packed in a cardboard carton. Pack size: 128 ml. The long tube version is supplied with a separate applicator with extension tube for attachment before use.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Chemidex Pharma Limited
Chemidex House
Egham Business Village
Crabtree Road
Egham
Surrey
TW20 8RB
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 1161/7/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd June 1983

Date of last renewal: 23rd June 2003

10 DATE OF REVISION OF THE TEXT

March 2008