

IRISH MEDICINES BOARD ACT 1995, as amended

Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended

PPA1500/026/001

Case No: 2083742

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

Profind Wholesale Ltd.

Unit 625, Kilshane Avenue, Northwest Business Park, Dublin 15, Ireland

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

Movicol 13.8g sachet, powder for oral solution

the particulars of which are set out in 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 **28/07/2010**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Movicol 13.8g sachet, Powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of Movicol contains the following active ingredients:

Macrogol 3350	13.125g
Sodium Chloride	350.7mg
Sodium bicarbonate	178.5mg
Potassium chloride	46.6mg

The content of electrolyte ions per sachet when made up to 125ml of solution is as follows:

Sodium 65 mmol/l

Chloride 53 mmol/l

Potassium 5.4 mmol/l

Bicarbonate 17 mmol/l

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for oral solution

Product imported from the UK

Free flowing white powder

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of chronic constipation. Movicol is also effective in resolving faecal impaction, defined as refractory constipation with faecal loading of the rectum and/or colon.

4.2 Posology and method of administration

Chronic constipation

A course of treatment for constipation with Movicol does not normally exceed 2 weeks, although this can be repeated if required.

As for all laxatives, prolonged use is not usually recommended. Extended use may be necessary in the care of patients with severe chronic or resistant constipation, secondary to multiple sclerosis or Parkinson's Disease, or induced by regular constipating medication in particular opioids and antimuscarinics.

Adults, adolescents and the elderly: 1 –3 sachets daily in divided doses, according to individual response.

For extended use, the dose can be adjusted down to 1 or 2 sachets daily.

Children below 12 years old: Not recommended. Alternative Movicol products are available for children.

Faecal impaction

A course of treatment for faecal impaction with Movicol does not normally exceed 3 days.

Adults, adolescents and the elderly: 8 sachets daily, all of which should be consumed within a 6 hour period.

Children below 12 years old: Not recommended. Alternative Movicol products are available for children.

Patients with impaired cardiovascular function: For the treatment of faecal impaction the dose should be divided so that no more than 2 sachets are taken in any one hour.

Patients with renal insufficiency: No dosage change is necessary for the treatment of constipation or faecal impaction.

Administration

Each sachet should be dissolved in 125 ml water. For use in faecal impaction 8 sachets may be dissolved in 1 litre of water.

4.3 Contraindications

Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, severe inflammatory conditions of the intestinal tract, such as Crohn's disease and ulcerative colitis and toxic megacolon. Hypersensitivity to the active ingredients or to any of the excipients.

4.4 Special warnings and precautions for use

Diagnosis of impaction/faecal loading of the rectum should be confirmed by physical or radiological examination of the abdomen and rectum. Mild adverse drug reactions are possible as indicated in Section 4.8. If patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) Movicol should be stopped immediately and electrolytes measured, and any abnormality should be treated appropriately.

4.5 Interaction with other medicinal products and other forms of interaction

No clinical interactions with other medicinal products have been reported. Macrogol raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water. There is therefore a theoretical possibility that the absorption of such medicinal products could be transiently reduced.

4.6 Pregnancy and lactation

There is no experience of the use of Movicol during pregnancy and lactation and it should only be used if considered essential by the physician.

4.7 Effects on ability to drive and use machines

Movicol has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Abdominal distension and pain, borborygmi and nausea, attributable to the expansion of the contents of the intestinal tract can occur. Mild diarrhoea which usually responds to dose reduction. Allergic reactions are a possibility.

4.9 Overdose

Severe pain or distension can be treated by nasogastric aspiration. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxatives.

ATC code: A06A D

Macrogol 3350 acts by virtue of its osmotic action in the gut, which induces a laxative effect. Macrogol 3350 increases the stool volume, which triggers colon motility via neuromuscular pathways. The physiological consequence is an improved propulsive colonic transportation of the softened stools and a facilitation of the defecation. Electrolytes combined with macrogol 3350 are exchanged across the intestinal barrier (mucosa) with serum electrolytes and excreted in faecal water without net gain or loss of sodium, potassium and water.

For the indication of faecal impaction controlled comparative studies have not been performed with other treatments (e.g. enemas). In a non-comparative study in 27 adult patients, Movicol cleared the faecal impaction in 12/27 (44%) after 1 day's treatment; 23/27 (85%) after 2 days' treatment and 24/27 (89%) at the end of 3 days.

Clinical studies in the use of Movicol in chronic constipation have shown that the dose needed to produce normal formed stools tends to reduce over time. Many patients respond to between 1 and 2 sachets a day, but this dose should be adjusted depending on individual response.

5.2 Pharmacokinetic properties

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastro-intestinal tract. Any macrogol 3350 that is absorbed is excreted via the urine.

5.3 Preclinical safety data

Preclinical studies provide evidence that macrogol 3350 has no significant systemic toxicity potential, although no tests of its effects on reproduction or genotoxicity have been conducted.

There are no long-term animal toxicity or carcinogenicity studies involving macrogol 3350, although there are toxicity studies using high levels of orally administered high molecular weight macrogols that provide evidence of safety at the recommended therapeutic dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acesulfame potassium (E950)

Lime and lemon flavour containing:

Acacia solids

Maltodextrin

Lime oil

Lemon oil

Citral

Citric acid

Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

The shelf life expiry of this product shall be the date shown on the sachet and outer carton of the product as marketed in the country of origin.

Reconstituted solution : 6 hours

6.4 Special precautions for storage

Sachet: Do not store above 25°C.

Reconstituted solution: Store at 2-8°C (in a refrigerator and covered).

6.5 Nature and contents of container

Laminate sachets contained in an over-labelled cardboard carton

Pack size 30 sachets.

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

Any unused solution should be discarded within 6 hours.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Profind Wholesale Ltd
Unit 625, Kilshane Avenue
Northwest Business Park
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PAA 1500/026/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 28th August 2009

10 DATE OF REVISION OF THE TEXT

July 2010