IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA1288/003/001
Case No: 2042926

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

Transferred from PA0375/002/001.

Madaus GmbH

51101 Cologne, **Germany**

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

Colofibre Granules

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 **30/11/2007** until **05/12/2008**.

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

Colofibre Granules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Seeds of *Plantago ovata*:	65.0	%w/w
Plantago ovata (husks):	2.2	%w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Granules
Fine-grained, yellow-brown granules with an aromatic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of patients requiring a high fibre diet regimen and as a bulk forming agent in the regulation of bowel function.

4.2 Posology and method of administration

For oral administration.

Colofibre Granules should be placed dry on the tongue and without chewing or crushing swallowed with a glass of water or warm drink. Colofibre Granules can be taken mixed just before consumption with yoghurt, ice-cream, porridge or any semi-solid food. The last dose should not be taken immediately before retiring to bed. Ensuring adequate daily fluid intake of 1-2 litres is recommended.

Adults and children over 12 years:

One to two standard 5ml spoonfuls after supper and if necessary before breakfast. In obstinate cases two 5ml spoonfuls six hourly for 1 to 3 days.

Elderly:

The adult dosage is appropriate.

Children 5-12 years:

One 5ml spoonful daily.

4.3 Contraindications

1. Use in patients with hypersensitivity to *Plantago ovata*.
2. Use in patients with intestinal obstruction or faecal impaction or colonic atony.

4.4 Special warnings and precautions for use

1. Use of this product must be accompanied by an increased fluid intake, particularly in patients with decreased intestinal motility. Use in elderly or debilitated patients may need supervision.
2. If symptoms persist, consult your doctor.
3. Special note for diabetic patients: Each 5ml spoonful of Colofibre Granules contains approximately 0.9g of sucrose.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6 Pregnancy and lactation

This product should not be used in pregnancy unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Abdominal distension and flatulence may occur. As with all psyllium products, allergic reactions may occur in rare cases.

4.9 Overdose

There is no information about overdosage with this product.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Plantago ovata seeds and husks contain large amounts of mucilage which takes up moisture in the intestinal tract thereby increasing the bulk of the faecal column and promoting peristalsis.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Caraway Oil
Sage Oil
Peppermint Oil
Acacia
Talc
Titanium Dioxide
Iron Oxide (Red)
Iron Oxide (Yellow)
Hard Paraffin
Liquid Paraffin
Sucrose

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Lacquered aluminium cans with inner lid and screw cap. Pack size: 250 g

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

Madaus GmbH
51101 Cologne
Germany

8 MARKETING AUTHORISATION NUMBER

PA 1288/3/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 December 1983

Date of last renewal: 06 December 2003

10 DATE OF REVISION OF THE TEXT

November 2007