Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Microlax Rectal Solution
Sodium Citrate 450mg/5ml
Sodium Lauryl Sulphoacetate 45mg/5ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml unit dose contains sodium citrate 450mg and sodium lauryl sulphoacetate 45mg.
Excipient: Contains Sorbic acid (E200) 5mg/5ml unit dose.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Rectal solution (enema)
A colourless, viscous liquid, containing small air bubbles, supplied in disposable 5 ml white low density capped polyethylene microeneema tubes with elongated nozzles.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The Microlax enema acts as a laxative through its faecal softening and lubricant properties. 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

Rectal.
Recommended dosage schedules.

Adults - One Microenema administered as necessary.

Children - As adults unless below the age of 3, when the nozzle should be inserted only half its length.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

1. Prolonged usage of the microenema may lead to irritation of the anal canal.
2. When used in children under 3 years old, the nozzle should be inserted only to half its length.
3. When used in patients with inflammatory or ulcerative conditions of the large bowel, or with acute gastrointestinal conditions, extreme caution should be exercised.
4. Lubricate the nozzle tip with some of the contents to aid insertion.

4.5 Interaction with other medicinal products and other forms of interaction

None Known
4.6 Fertility, pregnancy and lactation

No problems have been reported.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Occasionally, slight rectal burning has been observed. Individual cases of hypersensitivity have been reported.

4.9 Overdose

Overdose is unlikely given the physical limitations of the route of administration.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Aided by the detergent effects of the sodium lauryl sulphoacetate, the sodium citrate produces a softening of hard faces by releasing bound water. In around 15 minutes evacuation should occur, taking with it the Microlax, thereby limiting its action.

5.2 Pharmacokinetic properties

The ingredients contained in the preparation are not likely to be systemically absorbed, distributed or metabolised. The ingredients are excreted in faeces.

5.3 Preclinical safety data

No preclinical data of clinical relevance are available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Sorbitol (crystallising) (E420)
Glycerol (E422)
Sorbic acid (E200)
Water purified
6.2 Incompatibilities
Not applicable.

6.3 Shelf life
Unopened: 5 years
Once opened: Use immediately and discard any unused solution.

6.4 Special precautions for storage
Do not store above 25°C. Do not freeze.

6.5 Nature and contents of container
The microenema tubes are 5 ml, made from white low density polyethylene with a capped elongated nozzle. Packs of 1, 4, 12 or 50 micrenemas are provided. Not all pack sizes may be marketed.

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 AUTHORIZATION HOLDER
McNeil Healthcare (Ireland) Ltd.
Airton Road
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8 MARKETING AUTHORIZATION NUMBER
PA 0823/046/001

9 DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION
Date of first authorisation: 23 January 1998
Date of last renewal: 23 January 2008

10 DATE OF REVISION OF THE TEXT
September 2008