

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

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

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 microenema 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, or prior to surgical and diagnostic procedures or 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 the active substance or any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

Prolonged usage of the microenema may lead to irritation of the anal canal.

When used in children under 3 years old, the nozzle should be inserted only to half its length.

When used in patients with inflammatory or ulcerative conditions of the large bowel, or with acute gastrointestinal conditions, extreme caution should be exercised.

Lubricate the nozzle tip with some of the contents to aid insertion.

Seek medical advice if symptoms persist and avoid prolonged use.

Microlax contains sorbic acid which may cause local skin reactions, e.g. contact dermatitis which is a local irritation at the site of use.

4.5 Interaction with other medicinal products and other forms of interaction

Risk of intestinal necrosis with sorbitol and sodium polystyrene sulphonate (oral / rectal administration).

4.6 Fertility, pregnancy and lactation

As there is no relevant data available to evaluate the potential for foetal malformation or other foetotoxic effects when administered during pregnancy Microlax Rectal Solution should only be used as directed by a physician at the time of delivery. It is not known whether sodium citrate, sodium lauryl sulfoacetate are excreted in human milk.

4.7 Effects on ability to drive and use machines

Microlax has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

Adverse drug reactions identified during post-marketing experience with sodium citrate/ sodium lauryl sulfoacetate are included in the table below.

The frequencies are provided according to the following convention:

Very common $\geq 1/10$

Common $\geq 1/100$ and $< 1/10$

Uncommon $\geq 1/1,000$ and $< 1/100$

Rare $\geq 1/10,000$ and $< 1/1,000$

Very rare $< 1/10,000$

Not known (cannot be estimated from the available data)

Table 1: Adverse Drug Reactions Identified During post-Marketing Experience with sodium citrate/sodium lauryl sulfoacetate by Frequency Category estimated from clinical trials or epidemiology studies

Body system	Incidence	Reported adverse event
<i>Gastrointestinal Disorders</i>	<i>Not known</i>	<i>Abdominal pain^a Anorectal discomfort Loose stool</i>
<i>Immune System Disorders</i>	<i>Not known</i>	<i>Anaphylactic reactions Hypersensitivity reactions (e.g. Urticaria)</i>

a: Includes the PTs Abdominal discomfort, Abdominal pain, and Abdominal pain upper

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: www.hpra.ie.

4.9 Overdose

No symptoms of overdose have been identified from post-marketing data and scientific literature for this product, when used intrarectally.

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 faeces 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 AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

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9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 January 1998

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