SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Micralax Micro-enema

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium alkylsulphoacetate 0.90% w/v; sodium citrate 9.0% w/v.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Rectal emulsion

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Micralax is indicated whenever an enema is necessary to relieve constipation: in dyschezia, especially in bedridden patients; in geriatrics, paediatrics and obstetrics; and in preparation for X-ray examination, proctoscopy and sigmoidoscopy.

4.2 Posology and method of administration

Adults and children aged 3 years and over: Administer the contents of one micro-enema rectally, inserting the full length of the nozzle. No lubricant is needed as a drop of the mixture is sufficient.

Micralax usually works within 5 to 15 minutes, so make sure you are near a toilet before using it.

Always use a fresh tube of Micralax every time.

1. Lie down on your side with your knees drawn up towards your tummy or, if you prefer, sit on the toilet.
2. Pull or twist the cap off the tube.
3. If you want to lubricate the nozzle before inserting it, squeeze a drop of liquid out onto the nozzle.
4. Insert the full length of the nozzle into your back passage.
5. Gently squeeze the tube until it is empty.
6. Keep squeezing the tube as you pull the nozzle out of your back passage. This is to stop the medicine being drawn back into the tube.
7. Wait for the laxative to work (5-15 minutes)

4.3 Contraindications

Do not use in patients with inflammatory bowel disease.

4.4 Special warnings and precautions for use

None

4.5 Interaction with other medicinal products and other forms of interaction

None

4.6 Pregnancy and lactation

No special recommendations.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Tabulated list of adverse reactions

System organ class	Frequency	Adverse reaction
Immune system disorders	Not known	**Anaphylactic reaction** Hypersensitivity (e.g, Urticaria)

Excessive use may cause diarrhoea and fluid loss, which should be treated symptomatically.

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Micralax combines the action of sodium citrate, a peptidising agent which can displace bound water present in the faeces; sorbitol, which enhances this action, and sodium alkylsulphoacetate, a wetting agent.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Sorbitol, Glycerin, Sorbic Acid and Purified Water.

6.2 Incompatibilities

None

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at a temperature not exceeding 25°C.

6.5 Nature and contents of container

5 ml polythene micro-enema tubes, capped, and with elongated nozzles

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

RPH Pharmaceuticals AB,
Box 603,
101 32 Stockholm,

Sweden

8 MARKETING AUTHORISATION NUMBER(S)

PL 36301/0019

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28 June 1991 / 07/10/2002

10 DATE OF REVISION OF THE TEXT

07/01/2026