SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Sodium citrate/Sodium lauryl sulfoacetate/Sorbitol 90mg/12.9mg/893mg enema.

Microlax.

2. Qualitative and quantitative composition

Each ml of solution contains: 90 mg sodium citrate, 12.9 mg sodium lauryl sulfoacetate and 893 mg sorbitol.

For excipients, see 6.1.

3. Pharmaceutical form

Rectal enema.

A colourless, viscous solution.

4. Clinical particulars

4.1 Therapeutic indications

Microlax 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.

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

Always use a fresh tube of Microlax 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

No side effects have been reported. 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 the e-PV desktop applications (https://drive.google.com/file/d/16hwTz0587ZWtSWadbBAMwQPOD_KSExZP/view) or search for e-PV Mobile applications on the Google Play or Apple App Store.

4.9 Overdose

Not applicable.

5. Pharmacological properties
5.1 Pharmacodynamic properties

Pharmacological classification: 16.5.5 Combination laxatives

Microlax 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 lauryl sulfoacetate, a wetting agent.

5.2 Pharmacokinetic properties

No available data.

5.3 Preclinical safety data

Not applicable

6. Pharmaceutical particulars
6.1 List of excipients

Glycerol
Sorbic Acid
Purified Water.

6.2 Incompatibilities

None

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

Single-dose 5 ml polyethylene (LDPE) tubes with cannula and twist off seal.

6.6 Special precautions for disposal and other handling

No special requirements.

7. APPLICANT

Johnson & Johnson (Pty) Ltd.
241 Main Road Retreat
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8. MANUFACTURER

Famar Orleans
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9. REGISTRATION DETAILS

Zimbabwe registration number: 2023/16.6/6367

Zimbabwe category for distribution: Pharmacy Medicines (P.)

10. DATE OF REVISION OF THE TEXT

May 2023