MICROLAX

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

MICROLAX Microenema

COMPOSITION

Each 1 ml contains:

Sodium Citrate	90 mg
Sodium Lauryl Sulphoacetate 70 %	12,9 mg
Sorbitol Solution	893 mg

Preservative:

Sorbic Acid	0,1 % *m/v*

List of excipients:

Sorbic acid, glycerol, water.

CATEGORY AND CLASS

A11.6 Lubricants and faecal softeners

PHARMACOLOGICAL ACTION

MICROLAX attracts water into the faecal mass, thus producing a soft motion which may be easily evacuated.

INDICATIONS

For the relief of occasional constipation and for use as a bowel cleansing regimen in preparation for X-ray examination and rectoscopy.

CONTRAINDICATIONS

Patients with inherited fructose intolerance.

WARNINGS AND SPECIAL PRECAUTIONS

For rectal use only.

MICROLAX should not be used in the presence of abdominal pain, nausea or vomiting. This product should not be used for a period longer than one week, unless directed by a doctor. If you have noticed a sudden change in bowel habits that has persisted for a period of greater than 2 weeks, consult a doctor before using the enema. Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult a doctor.

Care should be taken when administering preparations containing sorbitol to patients with impaired kidney function or severe liver damage.

DOSAGE AND DIRECTIONS FOR USE

Adults and children

At a time selected by the doctor or the patient, the contents of one tube is introduced into the rectum.

Directions for use:

1. Twist and pull the seal off the nozzle.
2. Squeeze the tube slightly so that a drop of MICROLAX appears at the tip in order to provide lubrication for easier insertion.
3. In adults insert the nozzle completely into the rectum.

Note: for children under 3 years of age only half the length of the nozzle should be inserted into the rectum (as indicated on the nozzle).

4. Empty the entire contents of the tube into the rectum by squeezing the shoulder of the tube.
5. Withdraw the nozzle whilst keeping the tube completely compressed.

The desired effect usually occurs within five to fifteen minutes.

SIDE EFFECTS

Occasionally a slight rectal burning sensation has been observed.

Individual cases of hypersensitivity (general skin reaction with or without hypotension or respiratory distress) have been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Diarrhoea. Treatment is symptomatic and supportive.

IDENTIFICATION

MICROLAX Microenema is a colourless, viscous solution containing small air bubbles which is packed in a single-dose preparation filled in 5 ml disposable, white plastic tube with an applicator nozzle.

PRESENTATION

MICROLAX Microenema is available in cartons of four or twelve single-dose polyethylene disposable tubes, each containing 5 ml rectal solution. Each tube is supplied with a flexible cannula about 5 cm long.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Keep the tubes tightly closed

Keep out of reach of children.

REFERENCE NUMBER

E 911 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Johnson & Johnson (Pty) Ltd.

241 Main Road

RETREAT

7945

South Africa

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