SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Microlet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 5 ml:

Glycerol 0.625 g (12.5 %W/V), sodium citrate 0.450 g (9% W/V) and sodium laurylsulphoacetate 0.045 g (0.9% W/V)

Excipient with known effect:

Contains sorbate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Enema

A translucent gel supplied in 5 ml tubes.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Constipation.

4.2 Posology and method of administration

Posology

Adults and children aged 6 years and over: one tube as required.

Microlet is not intended for children under 6 years of age.

Method of administration

Route of administration: Rectal

Adults and children aged 6 years and over:

Lubricate the nozzle with some of the contents; insert the full length of the nozzle into the rectum and squeeze the tube until total contents have been administered.

When used in children the nozzle should be inserted to half its length only.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1
- Inflammatory or ulcerative bowel disease.
- Acute gastrointestinal conditions.

4.4 Special warnings and precautions for use

Excessive use of Microlet may cause diarrhea and fluid loss. In such cases, Microlet should be discontinued and appropriate therapy instituted.

Microlet contains sorbate which may cause local skin reactions, e.g. contact dermatitis.

4.5 Interaction with other medicinal products and other forms of interaction

Prolonged use may interfere with the absorption of some vitamins.

4.6 Fertility, pregnancy and lactation

Indicated for use in constipation in obstetrics.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Very occasionally, a slight cramp may occur. Prolonged use may lead to irritation of the anal canal.

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il

4.9 Overdose

Not applicable

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: A06AG20

Sodium citrate is a 'peptizing' agent which liberates water present in the faeces. Sorbitol enhances this action. Sodium laurylsulphoacetate is a wetting agent. Glycerol promotes peristalsis and evacuation of the lower bowel.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol, water, potassium sorbate

6.2 incompatibilities

None known

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Tube with twist-off nozzle cap.

Pack sizes: 12, 100, 500 x 5 ml tubes. Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Not applicable.

7. MARKETING AUTHORISATION HOLDER

Dexcel Ltd., 1 Dexcel Street, Or Akiva 30600, Israel

8. MARKETING AUTHORISATION NUMBER

047-20-23432-03

Revised in August 2021 according to MOH guidelines