



Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold without a physician's prescription

Microlet[®], enema

Each 5 ml tube contains:

Glycerol 0.625 g

Sodium citrate 0.450 g

Sodium laurylsulphoacetate 0.045 g

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

Take this medicine according to the instructions in section 3 "How to use the medicine?" in this leaflet. Consult the pharmacist if you need additional information. Refer to a doctor if the symptoms of your illness get worse or if they do not improve after a few days.

1. What is the medicine intended for?

The medicine is intended for the relief of constipation.

Therapeutic group: Laxative

Microlet works by softening the stool through absorption of water into the bowel.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredients (glycerol, sodium citrate, sodium laurylsulphoacetate), or to any of the other ingredients this medicine contains (see section 6).
- You suffer from an inflammatory bowel disease e.g., ulcerative colitis or Crohn's disease.
- You have ever suffered from an acute condition of bowel problems or stomach discomfort (other than constipation).

Special warnings regarding the use of the medicine:

Before the treatment with Microlet, tell the doctor if:

- You require vitamin supplements for any reason.
- You use **Microlet** too often and over a long period, it may cause diarrhoea and loss of fluids. If this happens, stop using the medicine and consult the doctor.

Prolonged use may cause dependence on laxatives.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Vitamin supplements, since prolonged use of **Microlet** may interfere with the absorption of some vitamins in your body.

Pregnancy and breastfeeding

Microlet can be safely used during pregnancy, before childbirth and while you are breastfeeding, but as with any medicine, consult the doctor before using it.

Important information about some of the ingredients of the medicine

Microlet contains sorbate which may cause local skin irritation (e.g. contact dermatitis).

3. How to use the medicine?

Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The usual recommended dosage is:

In adults and in children 6 years of age and over: one tube as required.

Do not exceed the recommended dose.

Do not swallow! This medicine is intended for external use only.

Opening directions:

Twist the tab at the end of the nozzle and pull until the tab tears.

Method of administration

Lubricate the nozzle with some of contents. It is recommended to lie on the side with knees drawn up towards the abdomen or to sit on the toilet, gently insert the full length of the nozzle into the rectum and squeeze the tube until it is empty. Continue squeezing while withdrawing the nozzle from the rectum, to avoid re-suction of the substance.

In children, insert only half the length of the nozzle into the rectum. Do not use in case of resistance during insertion.

Use the medicine immediately after opening the tube. If there is any left, discard it.

Microlet usually acts within 15 to 60 minutes. It is recommended to stay near the toilet after using the medicine.

Do not use **Microlet** frequently or for longer than one consecutive week without consulting the doctor.

How can you contribute to the success of the treatment?

Make sure to drink fluids throughout the day (6-8 cups) to help soften the stool, follow a diet rich in fibers and engage in physical activity.

If you have used an overdose of Microlet

- Overuse of **Microlet** may cause diarrhea and loss of fluids. If this happens, tell the doctor.
- Using **Microlet** too often and over a long period may cause irritation of the rectum, and can reduce the absorption of vitamins from food.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Microlet** may cause side effects. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

The use of **Microlet** does not usually cause side effects, but occasionally slight abdominal cramping may occur.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (EXP.) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store below 25°C
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, the medicine also contains:

Sorbitol, water, potassium sorbate

What the medicine looks like and what the package contains:

A clear liquid in a 5 ml plastic tube.

Approved package sizes: 12, 100, or 500 tubes in a package. Not all package sizes may be marketed.

Revised in August 2021 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

047-20-23432-03

Manufacturer and registration holder: Dexcel Ltd., 1 Dexcel Street, Or Akiva 3060000, Israel