#### Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

## **Meroken**<sup>®</sup>

#### Powder for preparation of a lemon-flavored solution

#### Active ingredients

Each bottle contains

polyethylene glycol 3350	315.0 g
sodium chloride	8.424 g
sodium bicarbonate	4.284 g
potassium chloride	1.118 g

Inactive ingredients and allergens: see section 6 'Additional information'.

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

This medicine has been prescribed for you; do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

This medicine is usually not intended for children and/or infants.

What is the most important information I should know about Meroken?

Meroken may cause severe side effects such as:

Severe loss of fluids (dehydration) and changes in salt (electrolyte) balance in the blood. These changes may cause:

- o abnormal heart rate which may result in death
- o convulsions, even if you have never had them before
- kidney problems

The chance of losing fluids and of change in electrolyte balance in the body when using **Meroken** increases if you have:

- heart conditions
- o kidney diseases

• if you are taking diuretics or nonsteroidal anti-inflammatory drugs (NSAIDs)

Consult a doctor immediately if you experience any of the following effects:

- o vomiting
- o dizziness
- o decreased frequency of urination
- o headache

For further information about the side effects, see the section 4 'Side effects'.

#### 1. What is this medicine intended for?

**Meroken** is a preparation intended for cleansing the bowels so that they are ready for examinations such as: colonoscopy, barium enema, etc.

Therapeutic group: osmotic laxative.

## 2. Before using this medicine

### Do not use the medicine if:

- you are sensitive (allergic) to the active ingredients or to any of the other ingredients in this medicine.
  - For the list of inactive ingredients, see section 6 'Additional information'.
- you have (toxic) colitis, problems with emptying the stomach, bowel perforation, bowel obstruction, very dilated bowels.

#### Special warnings about using this medicine

#### Do not use the medicine without consulting your doctor before starting treatment:

- if you have or have ever had impaired function of the digestive system
- in patients lacking a gag reflex, unconscious or semiconscious patients
- if you are sensitive to any food or medicine
- if you have heart conditions
- if you have ulcerative colitis
- if you have problems swallowing or gastric reflux or aspiration (penetration of food, saliva or stomach acids into the airways)
- if you have a history of seizures
- if you are in the process of withdrawing from alcohol
- if you have a low level of salt (sodium) in your blood
- if you have a kidney disease
- if you have any other medical condition

#### Additional warnings:

Do no take any medicines for <u>one</u> hour before drinking the solution.

#### **Drug interactions**

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- medicines to treat hypertension or heart conditions
- medicines to treat kidney diseases
- medicines to treat seizures
- diuretics
- nonsteroidal anti-inflammatory drugs (NSAIDs) for pain and inflammation
- other laxatives
- starch-based thickeners

#### Using this medicine and food

It is preferable not to eat solid food the day before the examination and 3-4 hours before drinking the solution. Do not eat two hours before drinking the solution and until the examination is completed.

Only drink clear fluids:

- o on the day before the examination
- when drinking the solution
- o after you have finished drinking the solution and until two hours before the examination

#### Pregnancy and breastfeeding

There is insufficient information about using **Meroken** during pregnancy and breastfeeding. If you are pregnant or breastfeeding, consult your doctor before using this medicine.

### 3. How to use this medicine?

Always use this medicine according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Preparation for the examination depends on the time your examination is scheduled for. Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage unless otherwise prescribed by a doctor is usually:

Drink the 3 liters of solution at a rate of one glassful (240 ml) every 10 minutes until the solution is finished. It is advisable to drink the whole glassful at a time.

#### Do not exceed the recommended dose.

Preparing the solution:

The pharmacist should open the bottle and add 2.7 liters of tap water or fill it up to the line at the top of the bottle marked 3 liters, then close the bottle and shake well until completely dissolved. The solution tastes better when chilled.

It is preferable not to eat solid food the day before the examination and 3-4 hours before drinking the solution.

You must not eat during the two hours before drinking the solution and until the examination is completed.

Only drink clear fluids:

- o on the day before the examination
- $\circ$  when drinking the solution

after you have finished drinking the solution and until two hours before the examination
The solution is lemon-flavored. Do not add any flavorings or other supplements to the solution.
Do not mix the solution with starch-based thickeners due to the fear of aspiration.

Bowel movements are expected to begin about one hour after drinking the first glass. Do not use undissolved powder that has not been diluted in water. Swallowing the undissolved powder may increase the risk of nausea, vomiting, and loss of fluids (dehydration).

#### If you have taken an overdose, or if a child has accidentally swallowed some medicine,

immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Adhere to the treatment as recommended by your doctor.

# Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.

## If you have any further questions about using this medicine, consult your doctor or pharmacist.

#### 4. Side effects

Like with all medicines, using **Meroken** may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

#### Consult your doctor immediately if you experience:

- allergic reactions (such as skin rash with irritation, skin inflammation) (rare).
- severe loss of fluids (dehydration) and changes in blood salts (electrolytes). These changes may cause:
  - o abnormal heart rate which may result in death
  - o convulsions, even if you have never had them before
  - kidney problems
  - vomiting
  - o dizziness

- less frequent urination than usual
- o headache
- digestive tract bloating
- o difficulty drinking clear fluids
- anal irritation, vomiting and persistent or disturbing intestinal cramps.
- being unable to drink the solution because of the side effects.

#### Additional side effects:

• nausea, abdominal pain.

These effects usually pass within a short time after taking the medicine. If the effects intensify, slow down or temporarily stop drinking until they pass.

This medicine causes watery stools so that the bowel is cleaned before the examination.

# If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (<u>www.health.gov.il</u>) which links to an online form for reporting side effects. You can also use this link: <u>https://sideeffects.health.gov.il</u>

#### 5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

#### Storage conditions:

- Store the powder at room temperature (25°C).
- Store the prepared dissolved solution in the refrigerator and use within 14 days of preparation.
- Store in the original package.

#### 6. Additional information

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

lemon flavor, sucralose powder.

#### What the medicine looks like and contents of the pack

A white to cream-colored powder.

The powder is packaged in a plastic (HDPE) bottle with a plastic cap. The powder is intended for dissolving in tap water to obtain 3 liters of a ready-to-drink solution.

#### Manufacturer and registration holder:

Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay 2624761.

## **Registration number of the medicine in the Ministry of Health's National Drug Registry:** 6236.27922

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