



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

This medicine can be sold without a physician's prescription

### **Fleet Enema 133**

Ready to use, prelubricated disposable enema

Each 100 ml contains:

Monobasic sodium phosphate monohydrate 16 gram

Dibasic sodium phosphate heptahydrate 6 gram

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

**Read this entire leaflet carefully before using this 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 this medicine?". Consult the pharmacist if you need additional information.

#### **1. What is the medicine intended for?**

The medicine is intended for cleansing the large intestine before surgery, childbirth or medical examinations.

**Therapeutic group:** enemas.

**Fleet Enema 133** acts by increasing the water content of the stool and in this way helps in cleansing the bowel.

#### **2. Before using the medicine**

**Do not use the medicine if:**

- You are **hypersensitive** (allergic) to the active ingredients or to any of the other ingredients this medicine contains (see section 6)
- You have a **swollen large bowel** (megacolon)
- You have a **narrowing or incomplete opening** of the rectum
- You have a **blockage** of the lower large intestine (Hirschsprung's disease)
- You have a suspected **blockage of the gut**
- You have **blockage of the gut or failure of normal bowel movements** (sometimes called paralytic ileus)
- You have been told by the doctor that you may have:
  - **Inflammation of the appendix** (appendicitis)
  - **A pierced/damaged or blocked gut**
  - **An active inflammatory bowel disease** (such as Crohn's disease or ulcerative colitis)
- You have undiagnosed **bleeding from the rectum**
- You have **significant kidney dysfunction**
- You have **congestive heart failure** (your heart is unable to properly pump blood to the various organs in the body)
- **You have recently suffered from dehydration, vomiting or nausea or felt thirsty**
- You have **stomach pain**
- The patient is under 12 years of age
- You are receiving other sodium phosphate preparations including sodium phosphate oral solutions or tablets

### **Special warnings regarding the use of the medicine**

#### **Before the treatment with Fleet Enema 133, tell the doctor if:**

- You are frail or elderly. You may need assistance from a carer or a healthcare professional to use **Fleet Enema 133**
- You have uncontrolled blood pressure
- You have a heart or kidney condition
- You suffer from ascites (excess fluid in the peritoneal cavity)
- You suffer from rectal ulceration or fissures (tears in the skin of the rectum)
- You have had bowel surgery (colostomy)
- You suffer from electrolyte disturbances (changes in the salt levels in the body such as a low level of calcium, a low level of potassium, a high level of phosphate or a high level of sodium)

Consult the doctor even if the conditions detailed above were applicable to you in the past. You may need to be closely supervised during treatment with the medicine. Prolonged use may cause dependence on laxatives.

### **Drug interactions**

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

- Medicines for the treatment of high blood pressure such as angiotensin-converting enzyme inhibitors (ACE) (e.g. enalapril, ramipril, lisinopril) and angiotensin receptor blockers (e.g. losartan, candesartan, eprosartan, irbesartan, olmesartan, telmisartan, valsartan) or medicines for treating angina (calcium channel blockers).
- Medicines to empty the bladder (diuretics).
- Certain medicines for treatment of mental disorders (lithium).
- Any other medicine that could cause dehydration or alter the salt levels (potassium, sodium, phosphate or calcium) in your body, known as electrolyte balance.
- Certain medicines given for cleaning the bowel (containing sodium phosphate). See also in section 2 "Do not use the medicine if".
- Medicines that may alter the rhythm of your heart (prolong the QT interval) such as amiodarone, arsenic trioxide, astemizole, azithromycin, erythromycin, clarithromycin, chlorpromazine, cisapride, citalopram, domperidone, terfenadine, procainamide.
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin or ibuprofen.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor or pharmacist before using this medicine.

### **Driving and using machines**

Although this medicine has no direct effect on your ability to drive or use machines, you should remain near toilet facilities after using this medicine.

### **Important information about some of the ingredients of this medicine**

This medicine contains 144 mg of sodium benzoate per bottle, equivalent to 108 mg in 100 ml. Sodium benzoate may cause local irritation of the skin.

This medicine also contains sodium methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

### **3. How to use this 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 one 133 ml bottle in 24 hours for adults and children from the age of 12 years and over.

#### **Do not exceed the recommended dose.**

Do not swallow! This medicine is intended for rectal use (for the rectum) only.

Do not use more than one enema in 24 hours without consultation with the doctor, as using more than one enema in a 24 hour period may be harmful.

#### **Method of administration:**

- Shake the bottle before use to disperse the sediment.
- Lie on the left side with both knees drawn up to the chest or slightly bent with the right leg drawn up.
- Remove the cover of the nozzle, gently insert the nozzle of the enema into the rectum and gently squeeze the bottle.

If you feel resistance while inserting the nozzle of the enema or while administering the solution – stop the procedure, so as to prevent injury to the rectum.

The urge to evacuate your bowels is usually achieved within 1 to 5 minutes.

Consult a doctor if you did not have bowel movements within 5 minutes of using the enema.

Remain near a toilet after using the medicine.

The bottle is for one time use, dispose of the bottle after use.

**Stop the use and refer to a doctor immediately if** after using the medicine you notice **bleeding in the rectum.**

**Make sure to drink plenty of clear fluids e.g. water, clear soups, herbal tea, black tea, black coffee or diluted fruit juice without pulp (but not red or purple colored), to avoid dehydration.**

In general, you should drink an amount of 250 ml (small glass) every hour until the effect of the medicine has worn off. Afterwards, you should drink clear fluids, preferably water, to satisfy your thirst, until after finishing the medical procedure or according to the doctor's instructions.

#### **If you have accidentally taken a higher dose**

If you have taken an overdose, or if you have accidentally swallowed the medicine or if a child has swallowed the medicine, proceed immediately to a doctor or a pharmacist.

Bring the package of the medicine with you.

If you have taken an overdose, you may suffer from dehydration, thirst, or muscle rigidity.

**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 **Fleet Enema 133** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Using **Fleet Enema 133** may very rarely (effects that appear in less than 1 in 10,000 users) cause:

- Hypersensitivity: allergic reactions (with or without rash)
- Dehydration
- Muscle twitches and spasms due to changes in the amounts of salts (electrolytes) in the blood
- Abdominal pain or abdominal bloating
- Gastrointestinal pain
- Nausea or vomiting
- Rectal itching, stinging, pain or discomfort
- Blisters
- Diarrhoea
- Chills

**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 via the link "דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form of adverse events reporting or via the following 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 under 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, this medicine also contains:**

Water purified, sodium benzoate, sodium methyl parahydroxybenzoate, propyl parahydroxybenzoate, sodium hydroxide

**What the medicine looks like and what the package contains:**

Clear solution (may contain white sediment). The bottle contains 133 ml of liquid.

Revised in October 2021 according to MOH guidelines.

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

034-95-22406-11

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