

Macrostop®

ORAL SOLUTION

Medical device



Macrogol 4000 125 g

250 ml bottle with a graduated measuring cup

SUGAR FREE

GLUTEN FREE

1. IDENTIFICATION, COMPOSITION AND SCOPE OF MD

1.1 DESCRIPTION AND INDICATIONS OF USE

MACROSTIP® oral solution is a medical device based on Macrogol 4000.

MACROSTIP® oral solution is indicated for the treatment of chronic constipation; Faecaloma (situation of rebellious constipation with stool accumulation at the rectum level and / or colon level confirmed by physical examination of abdomen and rectum); treatment of constipation with episodic or chronic colic.

1.2 CONTRAINDICATIONS AND LIMITATIONS FOR USE

Do not take **MACROSTIP® oral solution** in case of known hypersensitivity to raw materials, perforation and / or gastrointestinal obstruction, known gastric or intestinal lesions, severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis and toxic megacolon.

1.3 COMPOSITION

One bottle of 250 ml contains: macrogol 4000 125 g. Excipients: purified water, citric acid, flavor, sodium benzoate, potassium sorbate, sucralose.

1.4 MECHANISM OF ACTION

MACROSTIP® oral solution is a medical device with a laxative action that, through an osmotic mechanism, regularizes intestinal functions. It is not absorbed or fermented in the intestine; it does not irritate the mucosa and is eliminated in the faeces in an unmodified form. Thanks to its affinity for water, **MACROSTIP® oral solution** softens faeces facilitating evacuation. Its action is not reduced over time.

1.5 PACKAGING FORMATS

A package contains one bottle of 250 ml with a graduated measuring cup.

2. METHOD OF USE AND DOSE

Adults and children over 8 years:

20-40 ml of solution per day (equal to 10-20 g of Macrogol) to be taken preferably in a single administration in the morning.

Children between 4 and 7 years:

16-32 ml of solution per day (equal to 8-16 g of Macrogol) to be taken preferably in a single administration in the morning.

Children between 2 and 3 years:

8-16 ml of solution per day (equal to 4-8 g of Macrogol) to be taken preferably in a single administration in the morning.

Use in children under 12 years should preferably be under medical supervision.

Do not use **MACROSTIP® oral solution** for more than 30 consecutive days, If symptoms persist consult a doctor.

3. INTERACTIONS

There are not known interactions with drugs but it is advisable to take the product at least 2 hours before or after the intake of drugs as the osmotic power of macrogol and the induced increased speed of gastrointestinal transit can adversely affect their effectiveness. However, consult your doctor before taking **MACROSTIP® oral solution** in case of other therapies in place.

4. KNOWN SIDE EFFECTS

The medical device is well tolerated because its mechanism of action is physical / mechanical and does not depend on a systemic absorption.

Unwanted side effects such as indigestion, stomachache or grumbling, swelling, flatulence, nausea, vomiting, anal irritation and mild diarrhoea may occur while taking it. These effects improve by reducing the dose. In case of allergic reactions, discontinue the assumption of the product and contact the doctor. In case of any undesirable effect, inform your doctor or pharmacist.

5. STORAGE CONDITIONS

The expiry date is indicated on the package and on the sachet and it refers to the product in intact packaging, correctly stored. Do not use after this date or if the package is open or damaged. Keep the device tightly closed, in a cool and dry place, away from light and heat sources.

6. WARNING

During pregnancy and lactation, consult the doctor before taking the product. Keep out of reach and sight of children.

Avoid contact with eyes. Do not use the product after the expiration date. Do not use in case of damaged packaging.

Talk to your doctor before taking **MACROSTIP® oral solution** for treatment of fecaloma.

7. DISPOSAL

The expired product or to be disposal, must be handled according to the waste management regulations of the Local Competent Authority. The product or its packaging should not be released into the environment.



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