

Macrostop® SACHETS

Macrogol 4000 10 g
Powder for oral solution

Single use medical device



EXCIPIENTS FREE
SUGAR FREE
GLUTEN FREE
WITHOUT FLAVOR

1. IDENTIFICATION, COMPOSITION AND SCOPE OF MD

1.1 DESCRIPTION AND INDICATIONS OF USE

MACROSTIP® sachets is a medical device based on Macrogol 4000.

MACROSTIP® sachets 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); situations requiring complete cleansing and colon cleansing; treatment of constipation with episodic or chronic colic.

1.2 CONTRAINDICATIONS AND LIMITATIONS FOR USE

Do not take **MACROSTIP® sachets** in case of known hyper-sensitivity 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 sachet of 10 g contains macrogol 4000 10 g.

1.4 MECHANISM OF ACTION

MACROSTIP® sachets 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® sachets** softens faeces facilitating evacuation. Its action is not reduced over time.

2. PACKAGING FORMATS

A box with 30 single sachets of 10 g.

3. METHOD OF USE

Constipation: Dissolve the contents of 1 sachet in a glass of water (125 ml). Drink the solution thus reconstituted. It is possible to divide the daily dose into several administrations. We recommend to take **MACROSTIP® sachets** away from meals.

Cleansing of the colon: Take 175 ml every 10 minutes, until the 4 litres is exhausted. It is preferable that every single dose is ingested quickly. The preparation must be taken after a fast of 3-4 hours. In any case, do not take solid foods from 2 hours before the examination until the test is performed.

3.1 DOSE AND TIME OF ADMINISTRATION

Constipation:

Elderly, adults, and children from 12 years:

- 1 sachet (10 g) 1-3 times a day. In case of prolonged use, it is possible to reduce the dose to 1-2 sachets per day. Open the sachet along the dotted line and dilute the contents in 125 ml (about 1 glass of still water).

Children from 7 to 11 years:

- half sachet (5 g) 2 times a day. Dilute the contents in 50 ml (about half glass of still water).

Children from 3 to 6 years:

– half sachet (5 g) 1 times a day. Dilute the contents in 50 ml (about half glass of still water).

Use in children under 12 years should preferably be under medical supervision. Do not use **MACROSTIP® sachets** for more than 30 consecutive days, If symptoms persist consult a doctor.

Cleansing of the colon: *Adults:* 23 sachets dissolved in 4 litres of water (each sachet must be dissolved in 175 ml of water) to be taken in a single dose, the afternoon before the exam, or split in two doses, 2 litres the evening before the exam and 2 litres the morning of the exam.

3.2 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® sachets** in case of other therapies in place.

3.3 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, stomach-ache 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.

4. 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.

5. 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® sachets** for treatment of fecaloma and cleansing of the colon.

6. 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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