

MacroStip® psyllium

SACHETS

Single use medical device

Macrolog 4000 5 g + Psyllium Fiber 3 g

Powder for oral suspension



PRESERVATIVES FREE
GLUTEN FREE
WITH NATURAL AROMA
ORANGE FLAVOR

1. IDENTIFICATION, COMPOSITION AND SCOPE OF MD

1.1 DESCRIPTION AND INDICATIONS OF USE

MACROSTIP® psyllium is a medical device based on Macrolog 4000 and Psyllium fiber.

MACROSTIP® psyllium is indicated for treatment of occasional and chronic constipation for adults and children.

1.2 CONTRAINDICATIONS AND LIMITATIONS FOR USE

Do not take **MACROSTIP® psyllium** 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 9 g contains macrolog 4000 5 g, psyllium fiber 3 g. Excipients: fructose, magnesium stearate, natural aroma, sucralose.

1.4 MECHANISM OF ACTION

MACROSTIP® psyllium is a medical device with laxative action which, through an osmotic action, regularizes the intestinal functions. It is neither absorbed nor fermented in the intestine; it does not irritate the mucosa and it is eliminated in the stool in an unmodified form.

- Macrolog recalls, by osmosis, a high quantity of fluids in the intestinal compartment, hydrating the fecal mass and stimulating peristalsis.

- The mucilages contained into Psyllium fiber, absorbing the liquids recalled in the intestinal lumen by macrolog, increases in volume (up to about 30-40 times their dry volume) increasing and softening the fecal mass.

MACROSTIP® psyllium softens the faeces facilitating the evacuation. Its action is not reduced over time.

2. PACKAGING FORMATS

A box with 14 single sachets of 9 g

A box with 20 single sachets of 9 g

A box with 30 single sachets of 9 g

3. METHOD OF USE

Open a sachet and put the content into a glass with 200 ml of still water. Mix well for about 10 seconds and drink immediately after diluting the powder. The eventual increase in consistency of the solution is a characteristic of the product. In order to obtain an optimal result, it is advisable to drink 1-2 glasses of water after taking the product. It can be taken at any time of the day, at least half an hour before going to bed.

It is recommended to take **MACROSTIP® psyllium** away from meals.

3.1 DOSE AND TIME OF ADMINISTRATION

- *Adults*: 2 sachets per day, preferably morning and evening.

- *Children and teenagers from 6 to 14 years*: 1 sachet per day.

Use in children under 12 years should preferably be under medical supervision. The duration of treatment is approximately 2 weeks. In long-term treatment, the dose is 1 sachet per day.

MACROSTIP® psyllium should be used for no more than 30 consecutive days, if symptoms persist, consult a doctor.

3.2 INTERACTIONS

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. Furthermore, Psyllium seeds could enhance the effect of cholesterol-lowering and hypoglycemic products. However, consult your doctor before taking **MACROSTIP® psyllium** in case of other therapies in place, including oral contraceptives and drugs based on lithium.

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 a 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 sachet 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 device after the expiration date. Do not use in case of damaged packaging.

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.

 **Pharma Line S.r.l.**
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