PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Rafassal® 500 mg Suppositories

Rafassal® 1 gram Suppositories

Active ingredient:
Each Rafassal 500 mg suppository contains: 500 mg mesalazine.
Each Rafassal 1 gram suppository contains: 1 gram mesalazine.
The active ingredient is also called mesalamine or 5-aminosalicylic acid.
For the list of additional ingredients see section 6.

Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. What is the medicine intended for?

The medicine is intended for treatment and prevention of ulcerative colitis and of Crohn's disease.
Therapeutic group: anti-inflammatory medicine from the salicylate group.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient, to salicylic acid, to salicylates such as acetylsalicylic acid (aspirin), or to any of the additional ingredients the medicine contains (for the list of additional ingredients, see section 6).
- You suffer from a severe liver or kidney function impairment.

Special warnings regarding the use of the medicine:
Before starting (and during) treatment with the medicine, tell the doctor if:

- You suffer or have suffered in the past from lung problems, especially if you suffer from (bronchial) asthma.
- You suffer or have suffered in the past from an allergy to a substance called sulphasalazine, which is a substance related to the active ingredient mesalazine. In this case, close medical supervision is required. (If acute symptoms of intolerance occur, such as: abdominal pain or spasms, fever, severe headache, rash – stop the treatment immediately).
- You suffer or have suffered in the past from liver problems.
- You suffer or have suffered in the past from kidney problems.
- You have ever developed a severe skin rash or skin peeling, blisters and/or mouth ulcers after using medicines containing mesalazine (the active ingredient in Rafassal).

The active ingredient (mesalazine) may cause red-brown urine discoloration after contact with the bleaching agent sodium hypochlorite, for example in the toilet water. This is a chemical reaction which is harmless to the patient.

Additional warnings:

- During the treatment with the medicine, the doctor may decide on close medical monitoring (see "Tests and follow-up").
- Kidney stones may develop due to the use of the medicine. The symptoms may include pain in the sides of the abdomen and blood in the urine. Make sure to drink a sufficient amount of liquids during treatment with the medicine.
- Serious skin reactions including DRESS syndrome (drug reaction with eosinophilia and systemic symptoms), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis have been reported in association with mesalazine treatment. Stop using the medicine and refer to a doctor immediately if you notice these serious skin reactions (for the list of symptoms see section 4 "Side effects").
- If you experience strong or recurrent headache, disturbance of vision, or ringing/buzzing in the ears refer to your doctor immediately.

Children and adolescents: there is not much experience with the use in children. The use in children and adolescents aged 6 to 18 years is according to the doctor's instructions and will be determined according to their condition and body weight.

Tests and follow-up: before starting treatment and during treatment, you may need to undergo blood and urine tests, liver and kidney function tests.

Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. In particular, inform the doctor or pharmacist if you are taking the following medicines (note that the following list mentions the active ingredients in the medicines. If you are not sure whether you are using any of these medicines, please consult the doctor or pharmacist):

- Certain anticoagulant medicines (such as warfarin).
- Azathioprine, 6-mercaptopurine, thioguanine (medicines used for treatment of immune system disorders).

Pregnancy and breastfeeding:
If you are pregnant, think you are pregnant, are planning a pregnancy or are breastfeeding, consult the doctor before using the medicine.

- **Pregnancy:** there is insufficient information regarding the use of Rafassal in pregnant women. Rafassal should be used during pregnancy only at the doctor's discretion and under his guidance.
- **Breastfeeding:** there is insufficient information regarding the use of Rafassal in breastfeeding women. The medicine passes into breast milk. There may be hypersensitivity reactions in the breastfed baby, such as diarrhea. Therefore, Rafassal should only be used at the doctor's discretion and under his guidance. If the doctor has allowed you to breastfeed, and the baby develops diarrhea, stop breastfeeding.

Driving and use of machinery: the use of the medicine is not expected to affect the ability to drive or operate machinery.

3. How to use the medicine?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and manner of treatment with the medicine.
The standard dosage is usually: the dosage, treatment regimen and duration of treatment will be determined only by the doctor.
The dosage will be personally adjusted for you by the doctor, depending on your condition and your response to the treatment, which will be examined in periodic medical follow-ups and periodic tests.
This medicine should be used at set times as determined by the attending doctor.
Do not exceed the recommended dose.

Note:
Do not swallow! This medicine is intended for anal use. Do not halve the suppository.

Method of use:
Wash your hands thoroughly. Remove the wrapper of the suppository. The suppository can be moistened with a little water for easier insertion. Lie down on your side and insert the suppository deep into the anus using your finger. Wash your hands thoroughly after inserting the suppository.
Notes:

1. If the suppository is too soft to enable insertion, it can be cooled in the refrigerator for about 30 minutes or cooled under cold running water before removing the wrapper.
2. It is advisable to empty your bowels before inserting the suppository.
3. If the suppository comes out within the first 10 minutes, insert a new suppository.

If you accidentally used a higher dosage refer to a doctor who will advise you what to do. If a child accidentally swallowed the suppository, refer to a hospital emergency room immediately, and bring the medicine package with you.
If you forgot to use the medicine at the scheduled time, continue treatment according to the prescribed dosage. Do not use a larger dose in order to compensate for the forgotten dose.
Adhere to the treatment as recommended by the doctor. In order to get the maximum benefit from the medicine, it should be taken regularly and consistently, both during periods of inflammation flare-ups and as a preventive treatment during remission.
If you stop taking the medicine: abrupt discontinuation of the medicine is not recommended. Even if there is an improvement in your state of health, do not stop treatment with the medicine without consulting the doctor.
Do not use or take medicines in the dark! Check the label and the dose every time you take a medicine.
Wear glasses if you need them.
If you have further questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Rafassal Suppositories 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.

Stop the treatment and refer to the doctor immediately in the following cases:

- **General allergic reactions:** symptoms of an allergic reaction can include: high fever, skin rash, joint pain and/or breathing difficulties, lupus erythematosus syndrome or general inflammation of the large bowel (causing severe diarrhea and severe abdominal pain). These reactions are very rare.
- General malaise (worsening of your general health), especially one accompanied by fever and/or pain in the mouth and/or throat. These symptoms can very rarely indicate a drop in the number of white blood cells (**agranulocytosis**), a condition which may make you more susceptible to the development of a severe infection. Other blood cells may be affected (e.g. platelets or red blood cells, thereby causing **aplastic anemia or thrombocytopenia**) and may cause symptoms such as unexplained bleeding, purple spots or blotches under the skin and anemia (feeling of tiredness, weakness and pale appearance, especially of the lips and nails). A blood test can check whether these symptoms are caused by the medicine's effect on your blood. These effects are very rare.
- **Serious skin reactions** such as: reddish, non-elevated, round or target-like patches, often with central blisters, skin peeling, ulcers in the mouth, throat, nose, genitals and eyes, widespread rash, high fever and enlarged lymph nodes. These effects can be preceded by fever and flu-like symptoms. See also "Additional warnings" in section 2. These effects occur in an unknown number of patients (unknown frequency).
- Shortness of breath, chest pain, irregular heartbeat or swelling of the limbs which may indicate **hypersensitivity reactions in the heart** (including inflammation of the heart muscle or heart membrane). These effects are rare.
- **Kidney function problems** (can occur very rarely), e.g. change in the color or amount of produced urine, swelling of the limbs or sudden pain in the waist area (caused by a kidney stone). Occur in an unknown number of patients (unknown frequency).
- **Strong or recurrent headache, disturbance of vision, or ringing/buzzing in the ears.** These can be symptoms of increased pressure inside your skull (idiopathic intracranial hypertension) (unknown frequency).

Additional side effects:
Common side effects (occur in 1-10 users out of 100):

- Rash and itching.

Rare side effects (occur in 1-10 users out of 10,000):

- Abdominal pain, diarrhea, wind (flatulence), nausea, vomiting, constipation.
- Headache, dizziness.
- Photosensitivity, which is an increased sensitivity of the skin to the sun and to ultraviolet (UV) light.

Very rare side effects (occur in less than one user out of 10,000):

- Changes in kidney function, sometimes accompanied by swelling of the limbs or pain in the waist area.
- Inflammation of the pancreas, which can manifest by severe abdominal pain.
- An allergic and/or inflammatory reaction of the lungs, which can manifest, among other things, by shortness of breath, cough, wheezing or a shadow in the lungs, seen in an x-ray.
- Muscle and/or joint pain.
- Liver and/or bile flow impairments, which may cause abdominal pain and/or jaundice (which can be manifested by yellowing of the skin and of the white of the eye).
- Liver function problems (including inflammation of the liver, elevated levels of liver enzymes).
- Hair loss, balding.
- Numbness and tingling in the hands and feet (peripheral neuropathy).
- Reversible decrease in sperm production.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.
Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which leads to the online form for reporting side effects, or by clicking on the link:
https://sideeffects.health.gov.il/

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store at a temperature lower than 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains: Hard fat

What does the medicine look like and what does the package contain?
Cream-colored rectal suppositories (for use via the anus), in packages containing 15 or 30 suppositories.
Not all package sizes may be marketed.

Registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

Medicine registration number in the national medicines registry of the Ministry of Health:
Rafassal 500 mg Suppositories: 0511226439
Rafassal 1 gram Suppositories: 0695028345

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