

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

The medicine is dispensed without a doctor's prescription

PEPTOLITE CHEWABLE TABLETS 262 mg

PEPTOLITE SUSPENSION 262.5 mg/15 ml

Each tablet contains:

Bismuth Subsalicylate 262 mg

Each 15 ml of suspension contains:

Bismuth Subsalicylate 262.5 mg

*Inactive ingredients in the preparation - see section 6 in the leaflet.

Read this package insert carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions refer to your physician or pharmacist.

The medicine is intended for adults and children above 12 years of age. Below the age of 12, you should refer to your doctor.

The medicine must be used correctly. Consult the pharmacist if you need further information. Stop taking the medicine and contact the physician if signs of the illness (symptoms) get worse or do not improve after two days. Likewise, if the diarrhea is accompanied by high fever, if you experience ringing in the ears or loss of hearing.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended to relieve cases of diarrhea, nausea, flatulence, abdominal cramps, upset stomach and indigestion.

2. BEFORE USING THE MEDICINE:

☒ Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any other ingredients contained in the medicine.
- Do not use in children and adolescents up to 20 years of age for illnesses accompanied by fever such as flu and chickenpox (for fear of Reye's syndrome).
- The medicine contains salicylate. Do not use the medicine if you are allergic to salicylates (including aspirin) or if you are taking other preparations that contain salicylate.
- You have a stomach ulcer, bleeding, bloody or black stool.

Special warnings regarding use of the medicine:

- Before starting treatment with Peptolite tell the doctor if: you are pregnant or breastfeeding, you are suffering or have suffered in the past from impaired function of: the respiratory system (e.g. asthma), the kidney/urinary tract, the digestive system (e.g. stomach ulcer), the blood system (e.g. coagulation, etc.), gout, dehydration, if you have fever.
- you have mucus in the stool.
- If you are sensitive to any type of food or medicine, in particular to aspirin and salicylates, inform the physician before taking this medicine.
- If behavioral changes, accompanied with nausea and vomiting occur upon use of the medicine, consult the doctor since these symptoms can be an early sign of Reye's syndrome, a rare but serious disease.
- Do not give to children or adults for treatment of nausea of an organic background.
- Do not use the medicine if signs of the illness (symptoms) get worse or do not improve after two days.
- Do not use this medicine frequently or for a prolonged period without consulting the physician.

☒ If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, inform the physician or pharmacist. You must especially tell the physician or pharmacist if you are taking aspirin and salicylates, anticoagulants, medicines for gout, probenecid or sulfapyrazone, tetracyclines, medicines for diabetes, medicines for arthritis.

☒ Use of the medicine and food:

The medicine can be taken with or without food.

☒ Use of the medicine and consumption of alcohol:

Do not drink wines or alcoholic beverages during treatment with the medicine.

☒ Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, consult a physician before using the medicine.

☒ Important information about some of the ingredients of the medicine:

The medicine contains salicylate. Do not use it if you are sensitive to salicylates, including aspirin, or if you are taking other preparations that contain salicylate.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the physician or pharmacist if you are not sure.

- **The accepted dosage is generally:**

Peptolite, chewable tablets

- Adults and children above 12 years of age: 2 tablets.

As needed, this dosage can be repeated every half hour to an hour, up to 8 times (16 tablets) in any 24 hour period. Chew or allow the tablet to dissolve in the mouth and swallow!

Do not exceed the recommended dose.

Peptolite, suspension

- Adults and children above 12 years of age:
30 ml = 2 tablespoons (2 TBSP).
As needed, this dosage can be repeated every half hour to an hour, up to 8 times (240 ml or 16 tablespoons) in any 24 hour period.
- Children below 12 years of age: consult the doctor.
- Do not use the medicine for more than two days, unless instructed to do so by the doctor.
- Before use, shake well, then drink according to the recommended dosage. Be sure to measure the dose in the attached measuring cup. **Do not exceed the recommended dose.**

If you have accidentally taken a higher dose: If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine: If you forget to take this medicine at the required time, take a dose as soon as you remember, but under no circumstances should two doses be taken together!

- How can you contribute to the success of the treatment? In case of diarrhea, drink plenty of caffeine free fluids in order to make up for the loss of fluids.
- 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 regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS:

As with any medicine, use of Peptolite may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop use and refer to the physician immediately if:

- The following symptoms occur: weakness, convulsions, breathing problems, blurred vision, confusion, ringing in the ears or loss of hearing, severe constipation.

Stop use and refer to the physician as soon as possible if:

- Signs of overdose occur, such as drowsiness, headache.
- In case of diarrhea with high fever. This medicine may cause a change in the color of your stool or tongue. These changes are not a cause for concern.
- If any of the side effects worsens, or if you experience a side effect not mentioned in the leaflet, consult the physician.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects from Drug Treatment" found on

the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

In addition, you can report to Perrigo via the following address: www.perrigo-pharma.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless clearly indicated by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package or the bottle. The expiry date refers to the last day of that month.
- Store below 25°C.
- **Suspension:** can be used for 3 months after first opening.

6. ADDITIONAL INFORMATION:

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

Tablets: Calcium carbonate, wintergreen flavor, magnesium stearate, mannitol PWD unchil, red #27 D&C Al lake, sodium saccharin, stearic acid.

The amount of sodium in each tablet: 0.3 mg

Suspension: Magnesium aluminium silicate, methylsalicylate, methyl cellulose, D&C red 22, D&C red 28, sodium saccharin, salicylic acid, sodium salicylate, sorbic acid, xanthan gum, purified water.

The amount of sodium in each 30 ml: 12 mg

The amount of preservative in each 30 ml:

Sorbic acid 11.4 mg

How does the medicine look and what are the contents of the package?

Peptolite tablets: a package containing 12 or 24 or 30 pink flat tablets.

Peptolite suspension: a bottle containing 237 ml of pink viscous liquid.

Registration holder and address: Perrigo Israel Agencies Ltd., 29 Lehi Street, Bnei-Brak, 51200.

Name of manufacturer and address: Perrigo Company, Allegan, Michigan, USA.

This leaflet was checked and approved by the Ministry of Health in January 2015.

Drug Registration No. in the National Drug Registry of the Ministry of Health:

Peptolite tablets: 14841.33716

Peptolite suspension: 14688.33560