

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

The medicine is dispensed
without a doctor's prescription

PINK BISMUTH CHEWABLE TABLETS 262 mg

PINK BISMUTH 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 Pink Bismuth 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 sulfipyrazone,
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:**

Pink Bismuth, 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.**

Pink Bismuth, 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 Pink
Bismuth 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 aluminum 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?**

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

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

Registration holder and address:

Perrigo Israel Agencies Ltd., 29 Levi
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:

Pink Bismuth tablets: 12876.30717

Pink Bismuth suspension:
12877.30747