

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

The medicine is dispensed without a doctor's prescription

KALBETEN Suspension

Active ingredient and its concentration:
Each 15 ml contains:
Bismuth Subsalicylate 262 mg

KALBETEN FORTE Suspension

Active ingredient and its concentration:
Each 7.5 ml contains:
Bismuth Subsalicylate 262 mg

KALBETEN Tablets

Active ingredient and its amount:
Each tablet contains:
Bismuth Subsalicylate 262 mg

KALBETEN FORTE Caplets

Active ingredient and its amount:
Each caplet contains:
Bismuth Subsalicylate 524 mg

For details of other ingredients in the medicine see Section 6 - Further Information.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions refer to the doctor or pharmacist. The medicine is intended for adults and children above 12 years of age. Below the age of 12, you should refer to a doctor. The medicine must be used correctly. Consult the pharmacist if you need further information. Stop taking the medicine and refer to the doctor if signs of the illness (symptoms) worsen 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?

- Relief in cases of diarrhea, nausea, flatulence, abdominal cramps, upset stomach and indigestion.
- Prevention of traveler's diarrhea.

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 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 suffer from a stomach ulcer, bleeding, bloody or black stool.

Special warnings regarding use of the medicine:

- **Before starting treatment with Kalbeten inform 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.

- If you are sensitive to any type of food or medicine. In particular to aspirin and salicylates, inform the doctor before taking the medicine.
- Do not use this medicine for children and adolescents under 20 years of age suffering from flu or chickenpox, or if they have fever or have lost large amounts of fluids.
- Do not give to children or adults for treatment of nausea on an organic background.
- Do not use the medicine if signs of the illness (symptoms) worsen or do not improve after two days.
- Do not use this medicine frequently or for a prolonged period without consulting the doctor.

If you are taking, or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor 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 doctor 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 doctor or pharmacist if you are not sure.

The usual dosage is generally:

Kalbeten Tablets and Kalbeten Forte Caplets:

The usual dosage is generally:

Patient Age	Kalbeten Tablets	Kalbeten Forte Caplets
Adults and children above 12 years of age	2 tablets	1 caplet

For children below 12 years of age, consult a doctor. Following a doctor's recommendation - children below 9 years of age: use of liquid Kalbeten is recommended.

As needed, this dosage can be repeated every half hour to an hour, up to 8 times in any 24-hour period.

Swallow the medicine with water. Do not halve Kalbeten tablets.

Kalbeten Forte Caplets: The caplet can be divided to facilitate swallowing, but both parts must be swallowed together.

Do not exceed the recommended dose. Kalbeten Suspension and Kalbeten Forte Suspension:

The usual dosage is generally:

Patient Age	Kalbeten Suspension	Kalbeten Forte Suspension
Adults and children above 12 years of age	30 ml	15 ml

Children below 12 years of age: consult the doctor.

As needed, this dosage can be repeated every half hour to an hour, up to 8 times in any 24-hour period.

Shake well before use, then drink according to the recommended dosage. Be sure to measure the dose in the attached measuring cup or spoon.

Do not exceed the recommended dose.

If you accidentally took a higher dose: If you took 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. Do not induce vomiting unless explicitly instructed to do so by the doctor.

If you forget to take the medicine: If you forgot to take this medicine at the required time, take a dose as soon as you remember, but never take two doses 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 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 Kalbeten 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 doctor 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 doctor as soon as possible if:

signs of overdose occur, such as drowsiness, headache, in case of diarrhea accompanied by 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 suffer from a side effect not mentioned in the leaflet, consult with the doctor.

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 in order to avoid poisoning.

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 at room temperature up to 25°C.

6. FURTHER INFORMATION

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

Kalbeten Tablets: Mannitol, Povidone, Calcium Carbonate, Sodium Saccharin, Red Lake No. 3, Magnesium Stearate, Colloidal Silicon Dioxide, Polysorbate 80, Sodium Starch Glycolate, Microcrystalline Cellulose, Eudragit-E, Talc.

Each tablet contains approx. 1.5 mg sodium

Kalbeten Forte Caplets: Povidone, Sodium Starch Glycolate, Polysorbate 80, Calcium Carbonate, Microcrystalline Cellulose, Colloidal Silicon Dioxide, Magnesium Stearate, Red Lake No. 3, Opadry II.

Each caplet contains approx. 1.5 mg sodium

Kalbeten Suspension: Aluminium Magnesium Silicate, Carboxymethylcellulose Sodium, Propylene Glycol, Sorbic Acid, Benzoic Acid, Salicylic Acid, Saccharin Sodium, Sodium Salicylate, Ponceau, Methyl Salicylate, Purified Water. Each 15 ml contains approx. 7 mg sodium

Kalbeten Forte Suspension: Aluminium Magnesium Silicate,

Carboxymethylcellulose Sodium, Propylene Glycol, Sorbic Acid, Benzoic Acid, Salicylic Acid, Saccharin Sodium, Sodium Salicylate, Ponceau, Raspberry Flavour, Purified Water. Each 15 ml contains approx. 9 mg sodium

What does the medicine look like and what are the contents of the package?

Kalbeten Tablets: pink round tablets packed in a blister or a jar.

Kalbeten Forte Caplets: pink elongated caplets in a blister package.

Kalbeten Suspension: pink viscous liquid in a 100 ml bottle.

Kalbeten Forte Suspension: pink viscous liquid in a 100 ml bottle.

Manufacturer and license holder: Sam-On Ltd., 25 Ha-avoda Street, Bat-Yam.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Kalbeten Tablets: 114 90 29652

Kalbeten Forte Caplets: 140 95 31841

Kalbeten Suspension: 68 93 28288

Kalbeten Forte Suspension: 131 72 30868

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

10/03/09/0101