

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed without a doctor's prescription

### **Kalbeten Suspension**

Active ingredient and concentration:

Each 15 ml contains:

bismuth subsalicylate 262 mg

### **Kalbeten Forte Suspension**

Active ingredient and concentration:

Each 7.5 ml contains:

bismuth subsalicylate 262 mg

### **Kalbeten Tablets**

Active ingredient and quantity:

Each tablet contains:

bismuth subsalicylate 262 mg

### **Kalbeten Forte Caplets**

Active ingredient and quantity:

Each caplet contains:

bismuth subsalicylate 524 mg

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine.

If you have any further questions, consult your doctor or pharmacist.

You must use this according to the directions in the dosage section in this leaflet.

Consult your pharmacist if you need additional information. You should stop taking this medicine and consult your doctor if the signs of the disease (symptoms) worsen or do not improve after two days.

## **1. What is this medicine intended for?**

- For relief of diarrhoea, nausea, flatulence, convulsive stomach pains, indigestion and upset stomach.
- To prevent traveler's diarrhoea.

**Therapeutic group:** Adsorbents of fluids and toxins from the intestine and stools.

Kalbeten contains the active ingredient bismuth subsalicylate. It works by creating a soothing and protective coating of the stomach and intestine.

## **2. Before using the medicine:**

### **Do not use this medicine if:**

- you are sensitive (allergic) to the active ingredient, to salicylates, including aspirin or to any of the other ingredients in this medicine.
- You are taking other salicylates, including aspirin.
- You are pregnant or breastfeeding.

## **Special warnings about using this medicine**

**Before starting treatment with Kalbeten, tell your doctor if:**

- you have a blood clotting disorder or gout.

**Stop use and ask a doctor if:**

- the diarrhoea is accompanied by fever
- you have ringing in the ears
- you notice anything unusual or have unexpected side effects

**If you have diarrhoea**, it is important to prevent dehydration or treat it by drinking plenty of fluid or taking oral rehydration products, especially if you are frail or elderly.

**Children and adolescents**

This medicine is intended for adults and children over the age of 12. Under the age of 12, consult a doctor.

This medicine is not intended for use in children and adolescents who have or have recovered from chicken pox or flu-like symptoms. See section 4 'Side effects'.

**Drug interactions**

**If you are taking or recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.** Especially if you are taking aspirin and salicylates, blood thinning medicines (anticoagulants), medicines to treat diabetes, gout or tetracycline antibiotics.

**Using this medicine and food**

The medicine can be taken with or without food.

**Pregnancy and breastfeeding**

Do not use this medicine during pregnancy or while breastfeeding.

**Important information about some of this medicine's ingredients**

**Kalbeten Suspension and Kalbeten Forte Suspension:**

The medicines contain 20 mg/ml **propylene glycol**.

They also contain **Ponceau 4R**, a dye that may cause allergic reactions.

**3. How should you use the medicine?**

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. The recommended dosage is usually:

**Kalbeten Tablets and Kalbeten Forte Caplets**

The recommended dosage is usually:

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.

If recommended by the doctor - children under 9 years of age: use of liquid Kalbeten is recommended.

As needed, the dosage can be repeated every 30-60 minutes, up to 8 times every 24 hours.

Swallow the medicine with water.

Do not split Kalbeten tablets.

Kalbeten Forte Caplets: The caplet may be split to make swallowing easier, but both parts should be swallowed together.

**Do not exceed the recommended dose.**

### **Kalbeten Suspension and Kalbeten Forte Suspension:**

The recommended dosage is usually:

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 your doctor.

As needed, the dosage can be repeated every half hour to hour, up to 8 times every 24 hours.

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

**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 some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Do not induce vomiting unless explicitly instructed to do so by a doctor.

#### **Symptoms of overdose**

##### Bismuth intoxication

May present as acute encephalopathy with confusion, myoclonic movements, tremor, dysarthria and walking and standing disorders.

Bismuth intoxication may also cause gastrointestinal disturbances, skin reactions, discolouration of mucous membranes, and renal dysfunction as a result of acute tubular necrosis.

##### Salicylate poisoning

Common features include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation. Some degree of acid-base disturbance is present in most cases. A mixed respiratory alkalosis and metabolic acidosis with normal or high arterial pH (normal or reduced hydrogen ion concentration) is common effect in adults and children over the age of 4 years. In children aged 4 years or less, a dominant metabolic acidosis with low arterial pH (raised hydrogen ion concentration) is common. Acidosis may increase salicylate transfer across the blood brain barrier. Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopaenia, increased INR/PTR, intravascular coagulation, renal failure and non-cardiac pulmonary oedema.

Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.

#### **If you forget to take the medicine**

If you forget to take the medicine at the scheduled time, take a dose as soon as you remember, but under no circumstances should you take both doses together!

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

#### **4. Side effects**

Like with all medicines using Kalbeten may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Children and adolescents: If there are behavioural changes, including nausea and vomiting, while taking this medicine, consult your doctor since these symptoms may be an early sign of Reye's syndrome, a rare but serious disease.

#### **Additional side effects**

This medicine may cause a temporary and harmless change in the colour of your stools or tongue (a darker colour). If these symptoms do not pass within 3 days of stopping use of the medicine - **consult your doctor or pharmacist.**

**If any of the side effects gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il/>

#### **5. How to store the medicine?**

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package, blister or bottle.

The expiry date refers to the last day of that month.

**Storage conditions:** Store below 25°C.

#### **6. Additional information**

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

##### **Kalbeten Tablets**

microcrystalline cellulose, calcium carbonate, mannitol, sodium starch glycolate, povidone, colloidal silicon dioxide, magnesium stearate, polysorbate 80, Red Lake No. 3, sodium saccharin, Eudragit E 100, talc

##### **Kalbeten Forte Caplets:**

microcrystalline cellulose, calcium carbonate, sodium starch glycolate, povidone, colloidal silicon dioxide, magnesium stearate, polysorbate 80, Red Lake No. 3, Opadry II

##### **Kalbeten Suspension:**

Propylene glycol  
Aluminium magnesium silicate  
Carboxymethyl cellulose sodium  
Sodium salicylate  
Methyl salicylate  
Salicylic acid  
Sorbic acid  
Saccharine sodium  
Benzoic acid  
Ponceau 4R  
Purified water

##### **Kalbeten Forte Suspension:**

Propylene glycol  
Aluminium magnesium silicate  
Carboxymethyl cellulose sodium  
Raspberry flavour  
Sodium salicylate

Salicylic acid  
Sorbic acid  
Saccharine sodium  
Benzoic acid  
Ponceau 4R  
Purified water

**What the medicine looks like and contents of the pack?**

Kalbeten Tablets: round pink tablets with a score line on one side in a blister that contains 10, 20, 30, 40 tablets or a bottle that contains 10 tablets.

Kalbeten Forte Caplets: 5/10/20 oblong pink caplets with a score line on one side in a blister.

Kalbeten Suspension: pink viscous liquid in a 100 or 200 ml bottle.

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

**Not all pack sizes may be marketed.**

**Manufacturer and registration holder:** Sam-On Ltd., 25 Ehud Kinamon (Haavoda) St., Bat Yam.

Revised in      according to MOH guidelines.

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

Kalbeten Tablets:	114 90 29652
Kalbeten Forte Caplets:	140 95 31841
Kalbeten Suspension:	68 93 28288
Kalbeten Forte Suspension:	131 72 30868