

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

The medicine is dispensed with a doctor's prescription only.

## PROFITEN TABLETS

Each tablet contains:

**Ketotifen (as fumarate) 1 mg**

## PROFITEN SYRUP

Each teaspoon (5 ml) of syrup contains:

**Ketotifen (as fumarate) 1 mg**

Inactive and allergenic ingredients in the preparation - see section 6 in the leaflet.

**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.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The tablets are not intended for children under the age of 3. The syrup is not intended for children under 6 months of age.

## 1. WHAT IS THE MEDICINE INTENDED FOR?

As a prophylactic treatment of bronchial asthma. For symptomatic treatment of allergic conditions such as: bronchitis, rhinitis, hay fever, and skin rash (urticaria).

**Therapeutic group:** Other antihistamines for systemic treatment.

## 2. BEFORE USING THE MEDICINE

### ❑ Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see section 6 for a list of inactive ingredients).
- You are being concomitantly treated with oral anti-diabetic preparations.

### ❗ Special warnings regarding use of Profiten:

Since this medicine is intended for asthma prophylaxis, it is not effective in cases of acute asthma attacks. In such cases, use other preparations.

When you start treatment with Profiten, do not stop taking anti-asthma preparations you are currently using (especially preparations containing corticosteroids) without the doctor's permission.

### ❗ Before treatment with Profiten, tell the doctor if:

- You are pregnant, planning to become pregnant or are breastfeeding.
- You are suffering from epilepsy.
- You are suffering from a hereditary intolerance to certain sugars.

**❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** It is especially important to tell the doctor or pharmacist if you are taking:

- Oral anti-diabetic medicines.
- Medicines to treat insomnia or sedatives.
- Antihistamines to treat allergic reactions such as itching, rash or rhinitis.

### ❗ Use of the medicine and food

Take the medicine with a meal.

### ❗ Use of the medicine and alcohol consumption

Profiten may increase the effects of alcohol. Do not consume alcohol while using the medicine.

### ❗ Pregnancy and breastfeeding

If you are pregnant or planning to become pregnant, consult the doctor before using Profiten. Inform the doctor immediately if you become pregnant during the course of treatment with the medicine.

The medicine is excreted in breast milk; therefore, do not breastfeed while using the medicine.

### ❗ Driving and use of machinery

During the first few days of treatment, you may feel that your reactions are slower than usual. Some people may feel drowsy or dizzy. If you experience any effects, do not drive or perform any activity which requires alertness (e.g., operating tools or machines) until the effects pass. Children should be cautioned against riding a bicycle or playing near the road, and the like.

### ❗ Important information regarding some of the ingredients of the medicine

The tablets contain lactose. The syrup contains sucrose and sorbitol.

## 3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain. The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:

### Dosage for adults and children over 3 years of age:

1 tablet twice a day or 1 teaspoon of syrup (5 ml = 1 mg ketotifen) twice a day.

### Dosage for children from 6 months to 3 years of age:

½ teaspoon of syrup (2.5 ml = 0.5 mg ketotifen) twice a day.

### **Do not exceed the recommended dose.**

Take the medicine with a meal.

Tablets: Do not chew; can be halved or crushed. Swallow the medicine with a little water.

Syrup: Be sure to measure the dose in the provided measuring cup.

### **If you accidentally took a higher dosage**

If you took an overdose or if a child has accidentally swallowed the medicine,

immediately refer to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

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

If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose when you remember, unless it is almost time to take the next dose. If it is almost time to take the next dose, take the next dose as usual and skip the forgotten dose.

Adhere to the treatment regimen recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. Do not take medicines in the dark! Check the label and the dose each time you check the 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 Profiten 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.

**Discontinue use and refer to a doctor immediately** if you notice any of the following rare symptoms:

A severe skin reaction, which includes blistering or peeling of the skin. These may be symptoms of an allergic reaction.

Refer to a doctor immediately if you have an epileptic seizure.

### **Additional side effects**

Up to 1 in 10 people have experienced: Hyperactivity, agitation or irritability or sleep disturbances.

Up to 1 in 100 people have experienced: Cystitis (burning or pain when passing urine), dizziness or dry mouth.

Up to 1 in 1,000 people have experienced: Weight gain, drowsiness.

**Very rare side effects** that occur in less than one in 10,000 users:

Severe skin reactions including rashes, blistering or peeling of the skin; convulsions; liver problems, including jaundice or an increase in liver enzymes (will only be seen in a blood test).

Effects of drowsiness, dry mouth and dizziness usually pass a few days after starting treatment.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

### **Reporting side effects:**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://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=AdvrsEffectMedic@moh.gov.il>

In addition, you can report to Perrigo via the following address: [www.perrigo-pharma.co.il](http://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 safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store in the original package, in a cool place, below 25°C.
- **Profiten Syrup:** After first opening, can be used for the duration of two months.

## 6. FURTHER INFORMATION

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

### Profiten Tablets:

Lactose, starch (maize), poly vinyl pyrrolidone (PVP), talc, colloidal silicone dioxide, Na-starch glycolate, magnesium stearate.

Each tablet contains 52 mg lactose.

### Profiten Syrup:

Sucrose, purified water, sorbitol solution 70%, Optim glycerine 99.7%, sodium benzoate, citric acid, raspberry juice.

Each teaspoon (5 ml) of syrup contains 3 gram sucrose.

- What the medicine looks like and the contents of the package:

**Profiten Tablets:** A blister package containing 30 yellowish-white tablets with a score line on one side.

**Profiten Syrup:** A glass bottle containing 100 ml clear to yellowish, raspberry-flavored liquid.

- Registration holder and Manufacturer: Perrigo Israel pharmaceuticals Ltd., P.O.B. 16, Yeruham.

- This leaflet was checked and approved by the Ministry of Health in June 2016.

- Registration number of the medicine in the National Drug Registry of the Ministry of Health:

**Profiten Tablets:** 12610.26758

**Profiten Syrup:** 12526.26757