SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Profiten Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketotifen fumarate (equivalent to 1 mg ketotifen base).
For excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

White to slightly yellow scored tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylactic treatment of bronchial asthma.
Symptomatic treatment of allergic conditions including bronchitis, rhinitis, hay fever and urticaria.

4.2 Posology and method of administration

Adults

1mg twice daily with food. If necessary the dose may be increased to 2mg twice daily.

Children
From 3 years of age: 1 mg twice daily with food.
For patients for whom a tablet form may not be suitable, an alternative dosage form should be considered

Use in the elderly
No evidence exists that elderly patients require different dosages or show different side-effects from younger patients.

Patients known to be easily sedated should be given 0.5 -1 mg at night for the first few days.

4.3 Contraindications

Hypersensitivity to ketotifen or any of the excipients. A reversible fall in the thrombocyte count in patients receiving Profiten concomitantly with oral anti- diabetic agents has been observed in a few cases. This combination of drugs should therefore be avoided until this phenomenon has been satisfactorily explained.

4.4 Special warnings and precautions for use

Profiten Tablets contains Lactose. Patients with rare hereditary problems of galactose intolerance, of severe lactase deficiency or of glucose-galactose malabsorption should not take this medicine.

Convulsions have been reported very rarely during Profiten therapy. As Profiten may lower the seizure threshold it should be used with caution in patients with a history of epilepsy.

4.5 Interaction with other medicinal products and other forms of interaction

Profiten may potentiate the effects of sedatives, hypnotics, antihistamines and alcohol. Patients should be warned not to take charge of vehicles or machinery until the effect of Profiten treatment on the individual is known.

4.6 Fertility, Pregnancy and lactation

Although there is no evidence of any teratogenic effect, recommendation for Profiten in pregnancy cannot be given. Ketotifen is excreted in breast milk, therefore mothers receiving Profiten should not breast feed.

4.7 Effects on ability to drive and use machines

During the first few days of treatment with Profiten reactions may be impaired.
Patients should be warned not to take charge of vehicles or machinery until the effect of Profiten treatment on the individual is known.

4.8 Undesirable effects

Adverse reactions (Table 1) are ranked under heading of frequency, the most frequent first, using the following convention: very common (≥ 1/10); common (≥ 1/100,<1/10); uncommon (≥ 1/1,000<1/100); rare (≥ 1/10,000<1/1,000); very rare (<1/10,000), including isolated reports. Within each frequency grouping, adverse reactions are ranked in order of decreasing seriousness.

Infections and infestations	
Uncommon:	Cystitis
Immune system disorders	
Very rare:	Erythema multiforme, Stevens-Johnson syndrome, severe skin reaction
Metabolism and nutrition disorders	
Rare:	Weight increased
Psychiatric disorders	
Common:	Excitation, irritability, insomnia, nervousness
Nervous system disorders	
Uncommon:	Dizziness
Rare:	Sedation
Very rare:	Convulsions
Gastrointestinal disorders	
Uncommon:	Dry mouth
Hepatobiliary disorders	
Very rare:	Hepatitis, increase in liver enzymes

Sedation, dry mouth and dizziness may occur at the beginning of treatment, but usually disappear spontaneously with continued medication. Symptoms of CNS stimulation, such as excitation, irritability, insomnia, and nervousness, have been observed particularly in children.

4.9 Overdose

The reported features of overdose include confusion, drowsiness, nystagmus, headache, disorientation, tachycardia, hypotension, reversible coma; especially in children, hyperexcitability or convulsions. Bradycardia and respiratory depression should be watched for.

Treatment should be symptomatic. Treatment with activated charcoal should be considered if the overdose has been taken within approximately one hour. If necessary, symptomatic treatment and monitoring of the cardiovascular system are recommended; if excitation is present, short acting barbiturates or benzodiazepines may be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antihistamines for systemic use, ATC code: R06AX17

Profiten is a potent antiallergic drug which inhibits the effects of certain endogenous substances known to be inflammatory mediators. Profiten exerts a non-competitive blocking effect on histamine (H_1) receptors.

5.2 Pharmacokinetic properties

After oral administration the absorption of Profiten is nearly complete. Bioavailability amounts to approximately 50% due to a first pass effect of about 50% in the liver. Maximal plasma concentrations are reached within 2-4 hours. Protein binding is 75%. Ketotifen is eliminated biphasically with a short half-life of 3-5 hours and a longer one of 21 hours. In urine about 1% of the substance is excreted unchanged within 48 hours and 60-70% as metabolites. The main metabolite in the urine is the practically inactive ketotifen-N-glucuronide.

5.3 Preclinical safety data

Not stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not Known

6.3 Shelf life

48 months

6.4 Special precautions for storage

Store in a cool place below 25^{o}C

6.5 Nature and contents of container

PVC/PVDC blister pack (30 tablets).

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Perrigo Israel Pharmaceuticals Ltd
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8 MARKETING AUTHORISATION NUMBER(S)

12610.26758

25.5.16