Ketoresp Syrup

(K e t o t i f e n B P)

کیٹوریسپ سیرپ

(کیٹوٹائفن-بی پی)

COMPOSITION:

KETORESP Syrup 1mg/5ml:

Each 5ml contains:

Ketotifen hydrogen fumarate (BP) eq. to ketotifen.....1mg

Product complies Innovator's specs.

DESCRIPTION:

KETORESP contains ketotifen as hydrogen fumarate. Ketotifen is potent antihistaminic agent which exhibit strong H1 receptor blocking activity. Ketotifen is prepared synthetically. Ketotifen is effective in the preventive management for asthma and in the treatment of allergic conditions such as rhinitis and conjunctivitis. Ketotifen is administered orally.

INDICATIONS:

Preventative treatment of bronchial asthma especially when associated with atopic symptoms. **KETORESP** is not effective in aborting established attacks of asthma. **KETORESP** is not a substitute for corticosteroid treatment (inhaled or systemic) when corticosteroid is indicated in the treatment of asthma.

- Prevention and treatment of multisystem allergic disorders
- Chronic urticaria
- Atopic dermatitis
- Allergic rhinitis and conjunctivitis

DOSAGE AND ADMINISTRATION:

- **Use in Children**

Clinical observations reflect pharmacokinetic findings and indicate that children may require a dosage regimen similar to adults in order to obtain optimal results

- **Children aged 6 months to 3 years**

0.05 mg (= 0.25 mL syrup) per kilogram body weight twice daily (morning and evening). Example: an infant weighing 10 kg may receive 2.5 mL (= ½ teaspoonful) of **KETORESP** syrup, in the morning and evening.

- **Children over 3 years of age and adolescents**

5 ml (1 teaspoonful) syrup, or 1 tablet twice daily with morning and evening meal

- **Use In the elderly (age 65 years and above)**

There is no evidence to suggest that the dosage needs to be adjusted in elderly patients.

Efficacy guidance

In the prevention of bronchial asthma it may take several weeks of treatment to achieve the full therapeutic effect, it is therefore recommended that also for patients not adequately responding within a few weeks, treatment with **KETORESP** should be maintained for a minimum of 2 to 3 months.

Concomitant bronchodilator therapy

If bronchodilators are used concomitantly with **KETORESP**, the frequency of bronchodilator usage can be reduced:

If it is necessary to withdraw treatment with **KETORESP**, this should be done gradually over a period of 2 to 4 weeks. Symptoms of asthma may recur.

PHARMACOKINETIC PROPERTIES:

Absorption

After oral administration, the absorption of **KETORESP** is almost complete.

Bioavailability amounts to approximately 50% owing to a first-pass effect of about 50% in the liver. Maximal plasma concentrations are reached within 2 to 4 hours.

Distribution

- Protein binding is 75%.
- The main metabolite is the practically inactive ketotifen-N-glucuronide.

Elimination

Ketotifen is eliminated biphasically; with a short half-life of 3 to 5 hours and a longer one of 21 hours. About 1% of the substance is excreted unchanged in the urine within 48 hours and 60 to 70% as metabolites.

Effect of food

The bioavailability of either form of **KETORESP** (i.e. immediate or modified release formulations) is not influenced by the intake of food. Therefore **KETORESP** can be taken with or without food. However, smooth plasma concentration profile may be observed when administered with meals.

WARNINGS AND PRECAUTIONS:

Convulsions have been reported during **KETORESP** therapy. As **KETORESP** may lower the seizure threshold it is contraindicated in patients with a history of epilepsy.

Symptomatic and prophylactic anti-asthmatic drugs already in use should never be withdrawn abruptly when long-term treatment with **KETORESP** is begun. This applies especially to systemic corticosteroids, because of the possible existence of adrenocortical insufficiency in steroid-dependent patients; in such cases, recovery of a normal pituitary-adrenal response to stress may take up to 1 year. A reversible fall in the thrombocyte count in patients receiving **KETORESP** concomitantly with oral antidiabetic agents (biguanides) has been observed in rare cases. Thrombocyte counts should therefore be measured in patients concomitantly taking biguanides.

Effects on ability to drive and use machines

During the first few days of treatment with **KETORESP** the patient's reactions may be impaired and he/she should therefore exercise care when driving a vehicle or operating machinery.

SIDE EFFECTS:

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:	Agitation, irritability, insomnia, nervousness
Nervous System Disorders	
Uncommon:	Dizziness
Rare:	Sedation
Gastrointestinal Disorders	
Uncommon:	Dry mouth
Hepatobiliary Disorders	
Very rare:	Hepatitis, hepatic enzymes increased

DRUG INTERACTIONS:

- A reversible fall in the thrombocyte count in patients receiving **KETORESP** concomitantly with oral antidiabetic agents (biguanides) has been observed in rare cases. Thrombocyte counts should therefore be measured in patients taking **KETORESP** concomitantly with biguanides.
- **KETORESP** may potentiate the effects of CNS depressants, antihistamines, and alcohol.
- There is no data supporting any special recommendations in women of child-bearing potential.

Pregnancy

Although ketotifen was without effect on pregnancy and on peri- and post-natal development in animals at dose levels which were tolerated by the mother animals, its safety in human pregnancy has not been established. **KETORESP** should not be given to pregnant women except if clearly needed and the benefits outweigh the potential risks.

Breast-feeding

Ketotifen is excreted in rat milk. While there are no human data available, it is likely that this drug is also excreted in human breast milk, and therefore mothers receiving **KETORESP** should not breast-feed.

CONTRAINDICATIONS:

Known hypersensitivity to ketotifen or any of the excipients.

OVER DOSAGE:

Signs and symptoms

The main symptoms of acute overdose include: drowsiness to severe sedation; confusion and disorientation; tachycardia and hypotension; especially in children, hyper excitability or convulsions; reversible coma.

Treatment

Treatment should be symptomatic. If excitation or convulsions are present, short-acting barbiturates or benzodiazepines may be given. Monitoring of the cardiovascular system is recommended. If the drug has been taken very recently, emptying of the stomach may be considered. Administration of activated charcoal may be beneficial.

STORAGE & INSTRUCTIONS:

Store between 15-25°C in a cool and dry place. Protect from heat, sunlight & moisture.

Keep away from the reach of children.

To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED:

KETORESP Syrup 1mg/5ml:

60ml bottle.

خوراک وطریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۱۵۔۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان ٹھنڈی اور خشک جگہ پر رکھیں۔

دھوپ، گرمی اور نمی سے محفوظ رکھیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔

Manufactured by:

PHARMASOL

PRIVATE LIMITED

Plot # 549, Sundar Industrial Estate, Lahore, Pakistan.