

## KOFAREST-PED Drops

### COMPOSITION

|  |                |
|--|----------------|
| Each ml of <b>KOFAREST-PED Drops</b> contains: |                |
| Salbutamol                                     | 0.5 mg         |
| Ambroxol Hydrochloride                         | 7.5 mg         |
| Guaiphenesin                                   | 12.5 mg        |
| Menthol  | As syrupy base |

### PHARMACOLOGY

Salbutamol is a selective  $\beta$ -2-adrenoceptor agonist. At therapeutic doses it acts on the  $\beta$ -2-adrenoreceptors of bronchial muscle with little or no action on the  $\alpha$ 1-adrenoreceptors of cardiac muscle. Salbutamol stimulates the production of intracellular cyclic-AMP, enhancing the binding of intracellular calcium to the cell membrane and endoplasmic reticulum, resulting in bronchodilation. It also enhances mucociliary clearance.

Activation of the  $\beta$ -2-adrenoreceptors opens ATPase channels and drives potassium from the extracellular to the intracellular space. This both decreases extracellular hyperkalemia and increases intracellular potassium, so decreasing the chance of arrhythmia.

Ambroxol hydrochloride is a mucolytic agent, which liquefies thick, tenacious sputum. Ambroxol dissolves mucopolysaccharide fibers and thus reduces viscosity of sputum. It also improves mucociliary clearance of secretions.

Guaiphenesin is an expectorant. It increases the output of sputum and bronchial secretions by reducing adhesiveness and surface tension. By increasing the volume of bronchial secretions, it reduces the viscosity of tenacious sputum. The increased flow of less viscid secretions also promotes ciliary action.

Menthol has a cooling effect on the throat. It has been suggested that the benefits of menthol may be due to an effect on calcium channels of sensory nerves.

**KOFAREST-PED Drops** is an ideal combination. The ingredients are well absorbed after oral administration and provide prompt relief.

### INDICATIONS

**KOFAREST-PED Drops** is indicated for the treatment of productive cough associated with bronchospasm in conditions such as bronchitis and bronchial asthma as well as all conditions associated with tenacious mucus, wheezing and chest congestion.

### CONTRAINDICATIONS

**KOFAREST-PED Drops** is contraindicated in patients with hypersensitivity to any ingredient of the formulation.

### PRECAUTIONS

While treating cough as a symptom, it is important to make every effort to determine and treat appropriately the underlying cause, such as a specific infection.

Caution should be observed while prescribing **KOFAREST-PED Drops** to children with hypertension, cardiovascular disease, uncontrolled juvenile diabetes mellitus, hyperthyroidism, seizures or in patients who are unusually hypersensitive to sympathomimetic amines.

### **Pregnancy & Lactation**

Safety of **KOFAREST-PED Drops** has not been studied in pregnancy and lactation in humans. Therefore, probable benefits should be weighed against possible risks, before prescribing.

### **DRUG INTERACTIONS**

Hypokalemia with high doses of  $\beta_2$  -agonists may result in increased susceptibility to digitalis induced cardiac arrhythmias. Hypokalemia may be enhanced by concomitant administration of aminophylline or other xanthines, corticosteroids or by diuretic therapy.

Other sympathomimetic bronchodilators or epinephrine should not be used concomitantly with salbutamol, since their combined effect on the cardiovascular system may be deleterious to the patient.

Salbutamol should be administered with caution in patients being treated with monoamine oxidase (MAO) inhibitors or tricyclic antidepressants, since the action of salbutamol on the vascular system may be potentiated.

### **ADVERSE REACTIONS**

The adverse reactions to salbutamol are similar in nature to those of other sympathomimetic agents and include nervousness and tremor. The frequency of these side effects appears to diminish with continued therapy. Other commonly reported reactions include increased heart rate, palpitations, dizziness, headache, drowsiness, vomiting, nausea, sweating and muscle cramps. These reactions are generally transient and usually do not require treatment.

With ambroxol gastrointestinal side effects may occur occasionally and a transient rise in serum aminotransferase values has been reported.

Gastrointestinal discomfort has occasionally been reported with Guaiphenesin.

### **DOSAGE & ADMINISTRATION**

The usual recommended dose of **KOFAREST-PED Drops** in children is as under:

- ✦ 1-2 years age: 0.8 ml t.i.d.
- ✦ 2-3 years age: 1.2 ml t.i.d.

### **PRESENTATION**

**KOFAREST-PED Drops** is available in a bottle of 15 ml with calibrated dropper.