

Ofkof[®]

Antitussive Syrup

PRESCRIBING INFORMATION

Ofkof[®] Syrup is a mixture of antitussive, bronchodilator/decongestant and antihistamine agent. Dextromethorphan in **Ofkof[®]** syrup is a safe effective, non-narcotic antitussive agent which has a central action on the cough centre in the medulla. Although structurally related to morphine, it has no analgesic and habit forming properties and in general it has little sedative activity. Pseudoephedrine has direct and indirect sympathomimetic activity and is an effective upper respiratory decongestant. Pseudoephedrine is substantially less potent than ephedrine in producing both tachycardia and elevation of systolic blood pressure and considerably less potent in causing stimulation of the central nervous system. Triprolidine in **Ofkof[®]** Syrup provides symptomatic relief in conditions believed to depend wholly or partly upon the triggered release of histamine. It is a potent competitive histamine H₁-receptor antagonist of the pyrrolidine class with mild central nervous system depressant properties which may cause drowsiness.

Ofkof[®] Syrup is absorbed from the gastrointestinal tract and exerts its effect in 15-30 minutes. Dextromethorphan is metabolised in liver and excreted in the urine. Pseudoephedrine is largely excreted unchanged in the urine together with small amounts of its hepatic metabolite and triprolidine is metabolised in the liver and excreted usually as metabolites in the urine.

COMPOSITION

Ofkof[®] Syrup: Each 5 ml syrup contains Dextromethorphan Hydrobromide BP 10 mg, Pseudoephedrine hydrochloride BP 30 mg and Triprolidine hydrochloride BP 1.25 mg.

INDICATIONS

Ofkof[®] is indicated for the symptomatic relief of upper respiratory tract disorders accompanied by non-productive cough which benefits from the administration of a nasal decongestant, a histamine H₁ receptor antagonist and an antitussive combination.

DOSAGE AND ADMINISTRATION

Adults : 2 teaspoonful three times a day.
Children
Over 12 years: 2 teaspoonful three times a day.
6-12 years : 1 teaspoonful three times a day.
2-6 years : ½ teaspoonful three times daily or as directed by the physicians

A physician's advice should be obtained before administering **Ofkof[®]** to children less than 2 years.

CONTRAINDICATION

This combination is contraindicated in patients with a known hypersensitivity to dextromethorphan, pseudoephedrine or triprolidine. Contraindicated in persons under treatment with monoamine oxidase within 2 weeks of stopping such treatment. It is contraindicated in patients with severe hypertension or severe coronary artery disease.

SIDE EFFECT

Side-effects of Dextromethorphan appears to be rare and may include dizziness and gastrointestinal disturbances. Central nervous system (CNS) depression or excitation may occur, drowsiness being reported most frequently. Sleep disturbance and rarely hallucination have been reported. Skin rashes with or without irritation, tachycardia, dryness of mouth, nose and throat have occasionally been reported. Urinary retention has been reported occasionally in men receiving pseudoephedrine; prostatic enlargement could have been an important predisposing factor.

USE IN PREGNANCY AND LACTATION

There are no specific data on use of this combination during pregnancy. Caution should therefore be exercised by balancing the potential benefits of treatment of the mother against any possible hazards to the developing fetus.

PRECAUTION

This combination may cause drowsiness and impair performance in tests of auditory vigilance. It may also impair the patients ability to drive and also to use machineries. Although there are no objective data, users of this syrup should avoid the concomitant use of alcohol nor other centrally acting sedatives.

Although pseudoephedrine has virtually no blood pressure effect in patients with normal blood pressure, this combination should be used with caution in patients taking with antihypertensive agents, tricyclic antidepressants or other sympathomimetic agents such as decongestant, appetite suppressants and amphetamine like psychostimulants. As with other sympathomimetic agents caution should be exercised in patients with hypertension, heart disease, diabetes, hyperthyroidism, elevated intraocular pressure and prostatic enlargement.

This combination should not be used for persistent or chronic cough such as occurs with smoking, asthma, or emphysema or where cough is accompanied by excessive secretions unless directed by a physician.

DRUG INTERACTION

Concomitant use of this combination with sympathomimetic agents such as decongestants, tricyclic antidepressants, appetite suppressants and amphetamine - like psychostimulants or with monoamine oxidase inhibitors which interfere with the catabolism of sympathomimetic amines may occasionally cause a rise in blood pressure. Because of its pseudoephedrine content, this syrup partially reverse the hypotensive action of drugs which interfere with sympathetic activity including guanethidine, methyldopa, alpha-adrenergic blocking agents.

PHARMACEUTICAL PRECAUTION

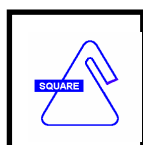
Store in a dry & cool place. Do not refrigerate. Protect from direct sunlight.

HOW SUPPLIED

Ofkof[®] syrup : PET bottle containing 100 ml syrup and a measuring cup.

® Registered Trade Mark

Manufactured by :



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH