

SCHEDULING STATUS: S2

PROPRIETARY NAME (AND DOSAGE FORM):

ADCO-TUSSEND (SYRUP)

COMPOSITION:

Each 5 ml contains:

Codeine phosphate	10 mg
Pseudoephedrine hydrochloride	30 mg
Tripolidine hydrochloride	1,25 mg

Preservatives:

Methyl hydroxybenzoate	0,12 % <i>m/v</i>
Propyl hydroxybenzoate	0,02 % <i>m/v</i>
Contains sugar: Liquid glucose	1,5 g
Sucrose	1,0 g

List of excipients: sodium saccharin, citric acid monohydrate, sodium citrate, raspberry red, strawberry flavour, sodium hydroxide pellets, purified water and sorbitol solution 70%.

PHARMACOLOGICAL CLASSIFICATION:

A.10.1 Antitussives and expectorants.

INDICATIONS:

For the alleviation of cough.

CONTRAINDICATIONS:

Persons who have previously exhibited intolerance to this product or to any of its constituents.

Patients suffering from cardiovascular disease (especially coronary insufficiency), hypertension, prostatism, thyrotoxicosis, bladder dysfunction, narrow angle glaucoma and phaeochromocytoma.

In patients with prostatic enlargement, it may increase difficulty with micturition (see **SIDE EFFECTS**).

Patients being treated with monoamine oxidase inhibitors and within two weeks of stopping such treatment; ephedrine and other sympathomimetic agents as a hypertensive response may result.

Acute alcoholism, during an acute attack of bronchial asthma, in patients with head injuries or where the intracranial pressure is raised, in heart failure secondary to chronic lung disease and in case of respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion.

WARNINGS AND SPECIAL PRECAUTIONS:

ADCO-TUSSEND syrup may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents (see **INTERACTIONS**). Patients should not drive, climb dangerous heights or operate machinery as impaired decision-making and impaired mental alertness could lead to accidents.

Pseudoephedrine should be given with caution to patients with organic heart diseases, cardiac decompensation or angina of effort and in patients receiving digitalis.

Large doses may precipitate fits in epileptics (see **SIDE EFFECTS**).

In infants and children it may act as a cerebral stimulant (see **SIDE EFFECTS**).

Do not use in children under 2 years of age.

Codeine should be given with caution to patients with hypothyroidism, adrenocortical insufficiency, impaired liver function, prostatic hypertrophy or shock. It should be used with caution in patients with inflammatory or obstructive bowel disorders. The dosage should be reduced in elderly and debilitated patients.

Exceeding the prescribed dose, together with prolonged and continuous use of this medication may lead to dependence and addiction.

ADCO-TUSSEND syrup should be used with caution in patients with diabetes mellitus, occlusive vascular disorders (arteriosclerosis), aneurysms, myasthenia gravis and impaired renal function.

ADCO-TUSSEND syrup should be used carefully in elderly and debilitated patients.

Do not give together with cardiac glycosides.

Do not give together with quinidine.

Do not give together with tricyclic antidepressant agent (see **INTERACTIONS**).

Contains liquid glucose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Contains sucrose: Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrose-isomaltase insufficiency should not take **ADCO-TUSSEND**.

Patient with the rare hereditary condition of sorbitol intolerance should not take **ADCO-TUSSEND**.

INTERACTIONS:

Pseudoephedrine should be used with caution in patients receiving chloroform, cyclopropane, halothane, or other halogenated anaesthetics. The effects of pseudoephedrine are diminished by guanethidine, reserpine and probably methyldopa and may be diminished or enhanced by tri-cyclic antidepressants. It may also diminish the effects of guanethidine and may increase the possibility of arrhythmias in digitalised patients.

ADCO-TUSSEND syrup may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents.

Triprolidine may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquilizers. The effects of anticholinergic drugs, such as atropine and tricyclic antidepressants may be enhanced by the concomitant administration of triprolidine. Triprolidine may affect the metabolism of drugs in the liver.

The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics and sedatives, and phenothiazines.

Concomitant use of **ADCO-TUSSEND** syrup with sympathomimetic agents, such as decongestants, appetite suppressants and amphetamine-like psychostimulants, or with monoamine oxidase inhibitors

which interfere with the catabolism of sympathomimetic amines, may cause a rise in blood pressure largely because of interaction with pseudoephedrine.

Because of its pseudoephedrine content, **ADCO-TUSSEND** syrup may partially reverse the hypotensive action of drugs which interfere with sympathetic activity including bretylium, bethanidine, guanethidine, debrisoquine, methyldopa and beta-adrenergic blocking agents.

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children over 12 years: 5 to 10 ml

Children 6 to 12 years: 5 ml

Children 2 to 5 years: 2,5 ml

May be given three times daily.

Not recommended for children under 2 years of age.

SIDE EFFECTS:

Fixed drug eruption due to pseudoephedrine, taking the form of erythematous nummular patches, and lichenoid skin eruption due to triprolidine have been reported.

Pseudoephedrine may give rise to side effects such as giddiness, headache, nausea, vomiting, sweating, thirst, tachycardia, precordial pain, palpitations, difficulty in micturition, muscular weakness and tremors, anxiety, restlessness and insomnia.

Pseudoephedrine may cause hypertension resulting in intracranial haemorrhage.

In patients with prostatic enlargement, it may increase difficulty with micturition.

Triprolidine can cause sedation varying from slight drowsiness to deep sleep, and including inability to concentrate, lassitude, dizziness, hypotension, muscular weakness, and inco-ordination. Other side effects include gastrointestinal disturbances such as nausea, vomiting, diarrhoea or constipation, colic, and epigastric pain, headache, blurred vision, tinnitus, elation or depression, irritability, nightmares, anorexia, difficulty in micturition, dryness of the mouth, tightness of the chest and tingling, heaviness, and weakness of the hands.

Symptoms of cerebral stimulation in adults include insomnia, nervousness, tachycardia, tremors, muscle twitching, and convulsions. Large doses may precipitate fits in epileptics. Allergy, anaphylaxis, and dermatological reactions may occur. Blood dyscrasias, including agranulocytosis and haemolytic anaemia have been reported. In infants and children it may act as a cerebral stimulant.

Codeine may cause nausea, vomiting, constipation, drowsiness, confusion, dry mouth, sweating, facial flushing, vertigo, bradycardia, palpitation, orthostatic hypotension, hyperthermia, restlessness, changes of mood and miosis. Micturition may be difficult and there may be ureteric or biliary spasm. Raised intracranial pressure may occur. Other side effects include circulatory failure, muscle rigidity, pruritus, respiratory depression, urticaria and an antidiuretic effect.

The following side effects may also occur: loss of appetite, reflex bradycardia, cardiac arrhythmias, cardiac arrest, confusion, dizziness, dyspnoea, fainting, fear, agitation, flushing, disturbance of glucose metabolism, irritability, miosis, dry mouth, psychotic states and weakness.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

The effects of acute toxicity from **ADCO-TUSSEND** syrup may include drowsiness, weakness, inco-ordination, difficulty with micturition, respiratory depression, hypotension, agitation, irritability, convulsions, hypertension, palpitations, tachycardia and miosis. Pseudoephedrine may cause paranoid psychosis. Treatment is supportive and symptomatic.

IDENTIFICATION:

Clear red syrup with strawberry flavour.

PRESENTATION:

Amber glass bottles containing 100 ml, 200 ml and 500 ml

STORAGE INSTRUCTIONS:

Store at or below 25 °C and protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

27/10.1/0256

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