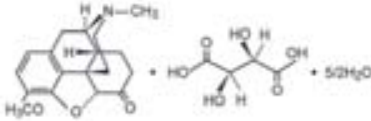


Excof[®]SF Liquid

Only CIII

DESCRIPTION: Excof[®]-SF Liquid is an alcohol-free, sugar-free, and dye-free syrup for oral administration having a strawberry aroma and fl avor. Each teaspoonful (5 ml) contains: Hydrocodone bitartrate (derivative of codeine) 5 mg , Phenylephrine HCl 8 mg, Carbinoxamine Maleate 4 mg

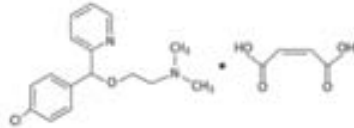
Hydrocodone Bitartrate: (Morphinan-6-one,4,5-epoxy-3-methoxy-17-methyl-, (5 α)-,[R-(R*, R*)]-2, 3-dihydroxybutanedioate (1:1), hydrate(2:5) is the bitartrate hemipentahydrate of hydrocodone. Its structure is as follows:



$C_{18}H_{21}NO_3 \cdot C_4H_6O_6 \cdot 2-1/2H_2O$

M.W. 494.49

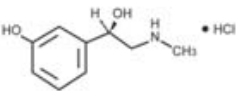
Carbinoxamine Maleate: (2-[(p-Chloro- α -[2-(dimethylamino) ethoxy]] benzyl] pyridine maleate) is one of the ethanolamine class of H1 antihistamines.



$C_{16}H_{19}ClN_2O \cdot C_4H_4O_4$

M.W. 406.87

Phenylephrine Hydrochloride: is a decongestant having the chemical name Benzenemethanol, 3-hydroxy- α -[(methylamino) methyl]-, hydrochloride (R)-.



$C_9H_{13}NO_2 \cdot HCL$

M.W. 203.67

Inactive ingredients: benzoic acid, citric acid, glycerin, menthol, propylene glycol, purified water, saccharin, sodium, sodium citrate dehydrate, sorbitol solution, strawberry flavoring.

CLINICAL PHARMACOLOGY:

Hydrocodone bitartrate is a narcotic antitussive providing cough relief. It acts in the medulla oblongata to elevate the cough threshold. Hydrocodone possesses narcotic analgesic properties; tolerance can develop and a potential for addiction exists. Hydrocodone is rapidly metabolized after ingestion, with trace amounts of unchanged drug in blood and urine.

Carbinoxamine maleate possesses H1 anti-histaminic activity and mild anticholinergic and sedative effects. Serum half-life for carbinoxamine is estimated to be 10 to 20 hours. Virtually

no intact drug is excreted in the urine.

Phenylephrine hydrochloride causes vasoconstriction by releasing norepinephrine from sympathetic nerve endings and by direct stimulation of alpha adrenergic receptors. It provides relief of nasal congestion by causing constriction of blood vessels and a reduction of blood supply to nasal mucosa, thereby decreasing the volume of blood in the sinusoids and the amount of mucosal edema. In therapeutic doses, the drug causes little central nervous system stimulation.

INDICATIONS AND USAGE: Excof[®]-SF Liquid is indicated for the temporary relief of symptoms such as cough, congestion, rhinorrhea associated with sinusitis, allergic rhinitis and the common cold.

CONTRAINDICATIONS: Patients with hypersensitivity or idiosyncrasy to any ingredients, patients taking monoamine oxidase (MAOI) inhibitors, patients with narrow- angle glaucoma, urinary retention, peptic ulcer, severe hypertension or coronary artery disease, or an intracranial lesion associated with increased intracranial pressure, or patients undergoing an asthmatic attack.

WARNINGS: Drug Dependence: May be habit-forming. Use with the same degree of caution as exercised with other narcotic containing medications since there is potential for drug dependence and abuse.

Respiratory and CNS Effects: May cause respiratory depression or an exaggerated increase in cerebrospinal fluid pressure in the presence of other intracranial pathology.

Use in Pregnancy: Safety for use during pregnancy has not been established.

Nursing Mothers: Use with caution in nursing mothers.

Special Risk Patients: Use with caution in patients with hypertension or eschemic heart disease, and persons over 60 years.

PRECAUTIONS: Antihistamines may cause drowsiness. Use with caution in ambulatory patients who operate machinery and in patients with severe impairment of liver or kidney function, hypothyroidism, thyroid disease, Addison's disease, hypertension, heart disease, asthma, or increased intraocular pressure, diabetes mellitus, prostatic hypertrophy or urethral stricture. Narcotics may obscure the diagnosis or clinical course in patients with acute abdominal conditions or head injuries.

Information for Patients: Patients receiving narcotic analgesics, alcohol, tranquilizers and other CNS depressants concomitantly with this product may exhibit CNS depression. Avoid alcohol while taking this product. Elderly or debilitated patients and those sensitive to narcotics should take this product with caution. Patients sensitive to antihistamines may experience moderate to severe drowsiness. Patients sensitive to sympathomimetic amines may note mild CNS stimulation. While taking this product, exercise care in driving or operating appliances, machinery, etc.

Drug Interactions: Antihistamines and narcotics such as hydrocodone may enhance the effects of tricyclic antidepressants, barbiturates, alcohol and other CNS depressants. MAOIs prolong and intensify the anti-cholinergic effects of reserpine, veratrum alkaloids, methyldopa and mecamlamine. Effects of sympathomimetics are increased with MAOIs and beta-

adrenergic blockers. The cough suppressant action of hydrocodone and other antitussives is additive.

Pregnancy Category C: Animal reproduction studies have not been conducted with Excof[®]-SF Liquid. It is also not known whether this medication can cause fetal harm when administered to a pregnant woman or affect reproduction capacity. Give to pregnant women only if clearly needed.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS:

Hydrocodone: Respiratory depression, sedation, dizziness, light-headedness, nausea, vomiting, constipation, skin rash, pruritus, euphoria and dysphoria.

Antihistamines: Sedation, dizziness, diplopia, vomiting, dry mouth, headache, nervousness, nausea, anorexia, heartburn, weakness, polyuria and dysuria and, excitability in children.

Sympathomimetic Amines: Convulsions, CNS depression, cardiac arrhythmias, respiratory difficulty, increased heart rate or blood pressure, hallucinations, tremors, nervousness, insomnia, weakness, pallor and dysuria.

DRUG ABUSE AND DEPENDENCE: Hydrocodone may be habitforming and can produce drug dependence of the morphine type, thereby having potential for abuse. Psychic dependence and tolerance may develop after repeated administration. Excof[®]-SF, a Schedule III controlled substance, is subject to the Federal Controlled Substances Act.

OVERDOSAGE: No information is available as to specific results of an overdose of Excof[®]-SF. The signs, symptoms and treatment described below are those of hydrocodone, and H1 antihistamine overdose.

Symptoms: Should narcotic effects predominate, respiratory depression may occur, characterized by a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration and cyanosis. Sleepiness, extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension may occur. Apnea, circulatory collapse, cardiac arrest and death may occur in severe cases. Should antihistamine effects predominate, central action constitutes the greatest danger. In the small child, symptoms include excitation, hallucination, ataxia, incoordination, tremors, flushed face and fever. Convulsions, fixed and dilated pupils, coma and death may occur in severe cases. In the adult, fever and flushing are uncommon; excitement leading to convulsions and postictal depression is often preceded by drowsiness and coma. Respiration is usually not seriously depressed; blood pressure is usually stable. Should sympathomimetic symptoms predominate, central effects include restlessness, dizziness, tremor, hyperactive reflexes, talkativeness, irritability and insomnia. Cardiovascular and renal effects include difficulty in micturition, headache, flushing, palpitation, cardiac arrhythmias, hypertension with subsequent hypotension and circulatory collapse. Gastrointestinal effects include dry mouth, metallic taste, anorexia, nausea, vomiting, diarrhea and abdominal cramps.

Treatment: a) Evacuate stomach contents as condition warrants. Activated charcoal may be useful. b) Maintain a nonstimulation environment. c) Monitor cardiovascular status. d) Do not give stimulants. e) Reduce fever with cool sponging. f) Intravenous naloxone, nalorphine or levallorphan may antagonize narcotic respiratory depression. g) If sedatives and anticonvulsants are necessary for control of CNS excitation and seizures, monitor respiratory status carefully because of possible additive effects with hydrocodone. h) Physostigmine may reverse anticholinergic symptoms. i) Further care is symptomatic and supportive.

DOSAGE AND ADMINISTRATION: The following dosage schedule is recommended for administration every 6 to 8 hours. Adults and Adolescents over 12 years of age: 1 teaspoon orally three to four times daily. Pediatric patients, 6-12 years of age: ½ teaspoon orally three to four times daily. Pediatric patients under 6 years of age: Use only as directed by physician. The dosage for children should not be repeated more than four times in a 24 hour period. Also, geriatric patients may be more sensitive to the effects of Excof[®]-SF Liquid; the usual adult dosage should be adjusted by a physician accordingly.

HOW SUPPLIED: Excof[®]-SF liquid is an alcohol-free, sugar-free, and dye-free syrup for oral administration having a strawberry aroma and flavor, and supplied in bottles of 16 fl oz. (473 ml) NDC 45985-661-16, and in 25ml sample bottles NDC 45985- 661-25.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSAGE, CONTACT A POISON CONTROL CENTER AND SEEK PROFESSIONAL ASSISTANCE IMMEDIATELY.

Dispense in a tight, light resistant container with a child-resistant closure as defined in the USP/NF.

Recommended Storage: Store at controlled room temperature 59° - 86°F (15° - 30°C).

Manufactured for:

Stewart-Jackson Pharmacal, Inc.,
Memphis, TN 38118

Manufactured by:

Sovereign Pharmaceuticals, Ltd.,
Ft. Worth, TX 76118

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