PROFESSIONAL INFORMATION FOR

CORYX (TABLETS)

SCHEDULING STATUS

S2

PROPRIETARY NAME (AND DOSAGE FORM)

CORYX (Effervescent tablets).

COMPOSITION

Each tablet contains:

Chlorpheniramine maleate	4 mg
Pseudoephedrine hydrochloride	50 mg
Aspirin	600 mg
Vitamin C (ascorbic acid)	330 mg

Contains sweetener (aspartame 53 mg per tablet).

Sugar free.

PHARMACOLOGICAL CLASSIFICATION:

A 5.8 Preparations for the common cold including nasal decongestants.

PHARMACOLOGICAL ACTION:

CORYX has analgesic, antipyretic, antihistaminic and decongestant properties.

INDICATION

For the treatment of symptoms associated with colds and influenza.

CONTRAINDICATIONS:

1. Sensitivity to any of the ingredients.
2. Patients with coronary disease, hypertension, cardiovascular disease, hyperthyroidism, epilepsy.
3. Pregnancy and breastfeeding.
4. **CORYX** effervescent tablets are also contraindicated in patients being treated with monoamine oxidase inhibitors or within 14 days of stopping such treatment.
5. Patients with peptic ulcers, haemophilia or intolerance (sensitivity) to aspirin, severe renal impairment and patients receiving oral anti-coagulant therapy.
6. Children under the age of 12 years.

WARNINGS:

1. Do not use for more than 10 days without consulting your doctor.
2. Prolonged use of high doses may lead to anaemia, blood discrasias, gastrointestinal heamorrhage, peptic ulceration, and renal papillary necrosis.
3. Patients suffering from kidney disease should take **CORYX** under medical supervision.
4. The use of this medicine may lead to drowsiness and impaired concentration which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants.

5. Aspirin has been implicated in Reye's syndrome, a rare but serious illness, in children and teenagers with chickenpox and influenza. A doctor should be consulted before **CORYX** is used in such patients.
6. PHENYLKETONURICS: CONTAINS PHENYLALANINE.

INTERACTIONS:

Please refer to the sections **"CONTRAINDICATIONS"** and **"SIDE EFFECTS AND SPECIAL PRECAUTIONS"**.

CORYX effervescent tablets may enhance the sedative effects of central nervous system depressants, including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and antipsychotics. It has an additive anti-muscarinic action with other anti-muscarinic drugs, such as atropine and some antidepressants (both tricyclics and monoamine oxidase inhibitors).

CORYX effervescent tablets could mask the warning signs of damage caused by ototoxic drugs such as aminoglycoside antibiotics.

CORYX effervescent tablets may suppress the cutaneous histamine response to allergen extracts and should be stopped several days before skin testing.

CORYX effervescent tablets may cause a hypertensive crisis in patients receiving monoamine oxidase inhibitors (including reversible inhibitors of monoamine oxidase A).

CORYX effervescent tablets should be avoided or used with care in patients undergoing anaesthesia with cyclopropane, halothane, or other volatile anaesthetics.

An increase of arrhythmias may occur if given to patients receiving cardiac glycosides, quinidine, or tricyclic antidepressants, and there is an increased risk of vasoconstrictor or -pressor effects in patients receiving ergot alkaloids or oxytocin.

Some of the effects of aspirin on the gastrointestinal tract are enhanced by alcohol.

CORYX effervescent tablets should be used with caution with the concurrent use of dipyridamole, metoclopramide, metoprolol, carbonic anhydrase inhibitors, corticosteroids, antacids and adsorbents, gold compounds, coumarin anticoagulants, sulfonylurea hypoglycaemic drugs, zafirlukast, methotrexate, phenytoin, valproate, uricosurics such as probenecid and sulfinpyrazone, NSAID's and mifepristone.

PREGNANCY AND LACTATION:

The safety of **CORYX** effervescent tablets in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children over 12 years: One tablet every 8 hours if necessary. Place one tablet in a glass of warm (or cold if so wished) water and allow to dissolve. Drink the contents immediately once the whole tablet has dissolved.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Pseudoephedrine hydrochloride – fear, anxiety, restlessness, tremor, insomnia, confusion, irritability, weakness and psychotic states. Appetite may be reduced and nausea and vomiting may occur.

Vasoconstriction with resultant hypertension. The rise in blood pressure may produce cerebral haemorrhage and pulmonary oedema. There may also be a reflex bradycardia, but stimulation of B_1-adrenergic receptors of the heart may produce tachycardia and cardiac arrhythmias, anginal pain, palpitations and cardiac arrest. Hypotension with dizziness and fainting and flushing may occur.

Difficulty in micturition and urinary retention, dyspnoea, altered metabolism, including disturbances of glucose metabolism, sweating and hypersalivation. Headache is also common.

Should be used with caution in patients with:

- hyperthyroidism
- cardiovascular disease such as ischaemic heart disease, arrhythmia or tachycardia
- occlusive vascular disorders, including arteriosclerosis, hypertension or aneurysms
- diabetes mellitus
- closed-angle glaucoma

Anginal pains may be precipitated in patients with angina pectoris.

Should be avoided or used with caution in patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics as they may induce ventricular fibrillation.

An increased risk of arrhythmias may occur given to patients receiving cardiac glycosides, quinidine or tricyclic antidepressants.

Chlorpheniramine maleate – Because **CORYX** effervescent tablets may produce sedation, patients should not operate machinery, drive cars, climb dangerous heights or perform potentially dangerous tasks where impaired decision making could lead to accidents. Other central nervous system depressants, such as narcotic analgesics, hypnotics, sedatives and tranquillizers, if taken concomitantly, will enhance sedation. Care should be observed when tricyclic anti-depressants, guanethidine, reserpine, methyldopa or atropine are taken concomitantly.

Other untoward reactions referable to central actions include dizziness, tinnitus, lassitude, incoordination, fatigue, blurred vision, diplopia, euphoria, nervousness, insomnia, and tremors.

Digestive tract – loss of appetite, nausea, vomiting, epigastric distress, and constipation or diarrhoea. Their incidence may be reduced by giving the drug with meals. Other side-effects include dryness of the mouth, throat and respiratory passages; urinary frequency and dysuria; palpitation; hypotension, headache; tightness of the chest; and tingling, heaviness, and weakness of the hands.

Aspirin – gastrointestinal disturbances such as nausea, dyspepsia, and vomiting. Irritation of the gastric mucosa with erosion, ulceration, haematemesis and melaena may occur. Slight blood loss is not usually of clinical significance but may, in a few patients, cause iron-deficiency anaemia during long-term salicylate therapy. **CORYX** should be given with care to patients with a history of peptic ulceration.

Some persons, especially asthmatics, exhibit notable sensitivity to aspirin which may provoke various reactions including urticaria and other skin eruptions, angioedema, rhinitis, and severe, even fatal, paroxysmal bronchospasm and dyspnoea. Persons sensitive to aspirin may not tolerate therapeutic doses.

Aspirin increases the bleeding time, decreases platelet adhesiveness, and, in large doses, may cause hypoprothrombinaemia. **CORYX** may enhance the activity of coumarin anticoagulants and oral anti-diabetic preparations and sulphonamides. **CORYX** diminishes the effects of anti-gout preparations such as probenecid and sulphinpyrazone.

Barbiturates and other sedatives may mask the respiratory symptoms of aspirin overdosage and have been reported to enhance its toxicity.

Vitamin C – is usually well tolerated. Large doses are reported to cause diarrhoea and other gastrointestinal disturbances and are associated with the formation of renal calcium oxalate calculi. Ascorbic acid should be given with care to patients with hyperoxaluria. Tolerance may be induced with prolonged use of large doses.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See **"SIDE EFFECTS"**.

CORYX overdosage may result in convulsions and hypertension in susceptible patients. Overdosage may also cause tachycardia, arrhythmias and anginal pain, nausea, dizziness, hyperventilation, respiratory alkalosis, metabolic acidosis, vomiting, irritation of gastric mucosa with dispepsia, haematemesis and melaena.

The patient must be taken to a doctor or hospital immediately as specialized treatment may be necessary. Treatment is supportive and symptomatic, the serum salicylate levels should be closely monitored and forced alkaline diuresis instituted if appropriate.

IDENTIFICATION:

Round, biplane, beige to lightly yellow-coloured effervescent tablets, producing a light-yellow solution with a pineapple flavour once dissolved in ± 200 ml of water.

PRESENTATION:

Effervescent tablets packed in an aluminium tube with a white plastic closure, packed in a printed carton box. Each tube contains 12 tablets. Each carton contains one tube (12's).

STORAGE DIRECTIONS:

Store in tube, tightly closed in a dry place below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

27/5.8/0435

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