Coderin®

Description
Loratadine is an antihistamine. It is a long acting tricyclic antihistamine with selective peripheral H_1- receptor antagonistic activity and no central sedative or anticholinergic effect. Pseudoephedrine acts as a decongestant. It constricts blood vessels, by decreasing blood flow and decreases congestion.

Uses
Coderin® tablet should be administered when both the antihistaminic properties of Loratadine and the nasal decongestant activity of Pseudoephedrine are desired.

Coderin® is indicated for the relief of following symptoms due to hay fever or other upper respiratory allergies:

- nasal congestion
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat
- swelling of nasal passages
- sinus congestion and pressure

Dosage and administration
Adults and children over 12 years:
Coderin® 5 tablet: One tablet twice daily (every 12 hours)
Coderin® 10 tablet: One tablet once daily and to be taken in the morning instead of night.
Patients with renal insufficiency (GFR <30 ml/min) should be given a lower initial dose (one Coderin® 5 tablet per day, or one Coderin® 10 tablet every alternate day) because they have reduced clearance of Loratadine and Pseudoephedrine.
Patients who have a history of difficulty in swallowing tablets or who have known upper gastrointestinal narrowing or abnormal esophageal peristalsis should not use Coderin® 10 tablet.

Use in pregnancy
Pregnancy category B: no evidence of risk in human is reported.

Paediatric use
Safety and effectiveness in children below the age of 12 years have not been established.

Use in patients approximately 60 years of age and older
The safety and efficacy of Coderin® tablet in patients greater than 60 years old have not been investigated in placebo-controlled clinical trials. The elderly is more likely to have adverse reactions to sympathomimetic amines.

Use in nursing mother
It is not known if this combination product is excreted in human milk. However, both Loratadine and Pseudoephedrine when administered alone passed into breast milk, so it should not be administered to lactating mother.

Precautions
Coderin® tablet should generally be avoided in patients with hepatic insufficiency. Patients with renal insufficiency should be given a lower initial dose because they have reduced clearance of Loratadine and Pseudoephedrine. As because the doses of this fixed combination product cannot be individually titrated and hepatic insufficiency results in a reduced clearance of Loratadine to a much greater extent than Pseudoephedrine.

Side effects
In general it is well tolerated. Clinical trial suggests a very low of adverse effects commonly reported is dry mouth, somnolence, insomnia, pharyngitis, dizziness, coughing, fatigue, nausea, nervousness, anorexia, dysmenorrheal and headache. Other less common side effects may include; increased sweating, thirst, back pain, chest pain, malaise, palpitations, hypertension, tachycardia, abdominal distension, altered taste, flatulence, myalgia, dry throat, agitation, micturation frequency etc.

Contraindications
Coderin® tablet is contraindicated in patients who are hypersensitive to any component of this product.

Warnings
Coderin® tablet should be used with caution in patients with hypertension, diabetes mellitus, ischemic heart disease, increased intraocular pressure, hyperthyroidism, renal impairment, or with accompanying hypotension may be produced by sympathomimetic amines.

Overdose
In the event of overdosage, general symptomatic and supportive measure should be instituted promptly and maintained for as long as necessary. Treatment of overdose would reasonably consist of emesis (ipecac syrup), except in patients with impaired consciousness, followed by the administration of activated charcoal to absorb any remaining drug. If vomiting is unsuccessful, or contraindicated, gastric lavage should be performed with normal saline.

Drug interactions
Coderin® tablet is contraindicated in patients taking monoamino oxidase (MAO) inhibitors and for 2 weeks after stopping use of an MAO inhibitor. The antihypertensive effects of beta-adrenergic blocking agents, methyldopa, reserpine and veaturm alkaloids may be reduced by sympathomimetics. Increased ectopic pacemaker activity can occur when Pseudoephedrine is used concomitantly with digitalis. Concomitantly administration of Erythromycin, Ketoconazole and Cimetidine increases plasma concentration of both Loratadine and Decarboethoxyloratadine. But there were no clinically relevant changes in the safety profile of Loratadine.

Pharmaceutical precautions
Store in a cool, dry place. Protect from light

Presentation
Coderin® 5 tablet: A round shaped extended release tablet. Each tablet contains Loratadine USP 5mg and Pseudoephedrine Hydrochloride BP 120mg.

Coderin® 10 tablet: A round shaped extended release tablet. Each tablet contains Loratadine USP 10mg and Pseudoephedrine Hydrochloride BP 240mg.

Packaging quantities
Coderin® 5 tablet: Carton of 50 tablets in Alu-PVC blister.
Coderin® 10 tablet: Carton of 50 tablets in Alu-PVC blister.

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ACI Limited
Narayanganj, Bangladesh

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