

FLU-DAY

Film Coated Tablets



Composition:

Each FLU-DAY Film Coated Tablet contains:

Paracetamol 325 mg.

Cetirizine HCl 5 mg.

Phenylephrine HCl 10 mg.

Pharmacological Properties:

FLU-DAY has a unique drug combination with Paracetamol with its both analgesic and antipyretic activity due to inhibition of the synthesis of prostaglandins in the central nervous system. Cetirizine is a potent antihistamine (selective H1 receptor antagonist), which inhibits allergic reactions. Phenylephrine is a sympathomimetic agent with mainly direct effects on adrenergic receptors. The sympathomimetic effect of Phenylephrine produces vasoconstriction which in turn relieves nasal congestion.

Pharmacokinetics:

Paracetamol is readily absorbed from the gastrointestinal tract. It is metabolized in the liver and excreted in the urine, mainly as glucuronide and sulphate conjugates.

Cetirizine HCl is rapidly absorbed, with a time to maximum concentration (Tmax) of about 1 hour after oral administration. Plasma protein binding of cetirizine is about 93%. The terminal half-life is approximately 10 hours. About two thirds of the dose are excreted unchanged in urine.

Phenylephrine is irregularly absorbed from the gastrointestinal tract and undergoes first-pass metabolism by monoamine oxidase in the gut and liver; orally administered Phenylephrine has reduced bioavailability. It is excreted in the urine almost entirely as the sulphate conjugate.

Indications:

FLU-DAY is indicated for the symptomatic treatment of allergic rhinitis, fever and nasal congestion.

Contraindications:

- Hypersensitivity to active substances or to any of the excipients.
- Severe coronary heart disease, cardiovascular disorders, and Severe hypertension.
- Patients with prostatic enlargement, closed angle glaucoma or hyperthyroidism.

Warnings & Precautions:

FLU-DAY should be used with caution in patient with:

- Cardiovascular disease and occlusive vascular disease like Raynaud's phenomenon.
- Diabetes mellitus.
- Renal or hepatic impairment.
- Asthma, chronic bronchitis or emphysema.

Pregnancy & Lactations:

Pregnancy: FLU-DAY should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus. Ask your doctor or pharmacist for advice before taking this medicine.

Lactations: FLU-DAY is not recommended during breast-feeding.

Drug Interactions:

- The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of Paracetamol.
- Monoamine Oxidase Inhibitors: High blood pressure may occur when used with Phenylephrine. Phenylephrine should not be given to patients being treated with MAOi or within 14 days of stopping such treatment.
- Phenylephrine may reduce the efficacy of beta-blockers and other antihypertensives.
- Tricyclic antidepressants: may increase the risk of cardiovascular side effects with phenylephrine.
- Cetirizine may potentiate the effects of alcohol and other CNS depressants.
- Cholestyramine: The speed of absorption of paracetamol is reduced by cholestyramine. Therefore, cholestyramine should not be taken within an hour of taking paracetamol.
- Metoclopramide and domperidone may increase the absorption of paracetamol. However, concurrent use need not be avoided.

Side Effects:

Administration of FLU-DAY at the recommended dose has minor undesirable effects on the central nervous system, including drowsiness, fatigue and headache.

Other side effects may include: dry mouth, nervousness, irritability and increased blood pressure.

Driving & Using Machines:

Objective measurements of driving ability and sleep latency have not demonstrated any clinically relevant effects at the recommended dose of 10 mg of Cetirizine daily.

However, patients who experience somnolence when using FLU-DAY should refrain from driving, engaging in hazardous activities, or operating machinery.

Dosage & Administration:

Adults and children above 12 years: One tablet two times daily or as recommended by the physician.

The recommended dosage should not be exceeded.

Overdose

Symptoms: Symptoms observed after an overdose of cetirizine are: Confusion, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, somnolence, stupor, tachycardia, tremor, and urinary retention. Phenylephrine overdose is likely to result in effects similar to those listed under side effects. Additional symptoms may include hypertension and possibly reflux bradycardia. In severe cases confusion and seizures may occur. Symptoms of paracetamol overdose in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death.

Treatment: Patients should be referred to hospital urgently for immediate medical attention. Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol.

Storage:

Keep out of reach of children. Store below 25°C and in the original package.

Packaging:

Each FLU-DAY carton box contains 20 Film Coated Tablets in two blister strips.

