

LEZYNCET-D

To be sold by retail on prescription of R.M.P only

Abbreviated Prescribing information for LEZYNCET-D (Levocetirizine Hydrochloride & Phenylephrine Hydrochloride Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Levocetirizine, the (R) enantiomer of cetirizine, is a potent and selective antagonist of peripheral histamine (H₁)-receptors. H₁ receptors are activated by the biogenic amine histamine. Levocetirizine prevent binding of histamine to this receptors and this in turn prevent relief from the typical symptoms of allergic rhinitis. Phenylephrine is a potent vasoconstrictor that acts almost exclusively by stimulation of alpha-1-adrenergic receptors. Phenylephrine is a direct-acting sympathomimetic decongestant.

DOSAGE AND ADMINISTRATION:

Adults and adolescents 12 years and above

The daily recommended dose is one film-coated tablet. Lezyncet D is not recommended in children below 12 years of age.

CONTRAINDICATION: Known hypersensitivity to levocetirizine, phenylephrine or to any of the excipients. Severe renal impairment at less than 10 ml/min creatinine clearance. concomitant use of other sympathomimetic decongestants, tricyclic antidepressants or beta blocking drugs and monoamine oxidase inhibitors. Pheochromocytoma, Angle closure glaucoma.

WARNINGS & PRECAUTIONS: Concurrent intake of alcohol, urinary retention, epilepsy. This product should not be used by patients taking other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like psychostimulants).

DRUG INTERACTION:

Levocetirizine: No interaction studies have been performed with levocetirizine (including no studies with CYP3A4 inducers); studies with the racemate compound cetirizine demonstrated that there were no clinically relevant adverse interactions (with antipyrine, azithromycin, cimetidine, diazepam, erythromycin, glipizide, ketoconazole and pseudoephedrine).

Phenylephrine: Hypertensive interactions occur between sympathomimetic amines such as phenylephrine and monoamine oxidase inhibitors. Concomitant use of phenylephrine with other sympathomimetics amines can increase the risk of cardiovascular side effects. Phenylephrine may reduce the efficacy of beta-blocking drugs and antihypertensive drugs. Tricyclic antidepressants (eg amitriptyline) may increase the risk of cardiovascular side effects.

ADVERSE REACTIONS: Headache, somnolence, mouth dry, fatigue, asthenia, abdominal pain, constipation, nausea, vomiting, diarrhoea, hypersensitivity including anaphylaxis, aggression, agitation, hallucination, depression, insomnia, suicidal ideation, nightmare, convulsion, paraesthesia, syncope, tremor, dysgeusia, nervousness, dizziness, bradycardia, hypertensive episodes, tachycardia, dysuria, urinary retention, angle closure glaucoma.

MARKETED BY:

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(Additional information is available on request)