UNIAZ BETA

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **UNIAZ BETA** (Azelnidipine & Metoprolol Succinate (Sustained Release) Tablets (8+25 & 8+50, 16+25 & 16+50)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: ***Azelnidipine*** Azelnidipine represents lowering of the blood pressure by expanding the blood vessels based on L type and T type Ca channel antagonizing effect (inhibits trans-membrane Ca^{2+} influx through the voltage-dependent channels of smooth muscles in vascular walls). ***Metoprolol Succinate*** Metoprolol is a β1-selective (cardioselective) adrenergic receptor blocking agent. This preferential effect is not absolute, however, and at higher plasma concentrations, metoprolol also inhibits β2-adrenoreceptors, chiefly located in the bronchial and vascular musculature. The mechanism of the antihypertensive effects of beta-blocking agents has not been elucidated. However, several possible mechanisms have been proposed: (1) competitive antagonism of catecholamines at peripheral (especially cardiac) adrenergic neuron sites, leading to decreased cardiac output; (2) a central effect leading to reduced sympathetic outflow to the periphery; and (3) suppression of renin activity.

INDICATIONS: For the treatment in stage 2 Hypertension.

DOSAGE AND ADMINISTRATION: The recommended dose is 1 tablet once daily or as directed by the physician. For oral administration only.

CONTRAINDICATION: Hypersensitivity to any of the active substance (s) or to any of the excipient of the formulation. Metoprolol is contraindicated in severe bradycardia, second- or third-degree heart block, cardiogenic shock, decompensated heart failure, sick sinus syndrome (unless a permanent pacemaker is in place), and in patients who are hypersensitive to any component of this product.

WARNINGS & PRECAUTIONS: ***Azelnidipine:*** with your blood pressure dropping, you may feel dizzy and lightheaded. Do not work at heights, drive a car or operate dangerous machinery while you take this medicine. Do not drink grapefruit juice because it may increase drug blood concentration and cause an excessive hypotensive response. Hepatic function disorder with elevations of AST (GOT), ALT (GPT), γ-GTP, and jaundice may occur. ***Metoprolol:*** *abrupt cessation of therapy* with certain beta-blocking agents, exacerbations of angina pectoris and in some cases, myocardial infarction has occurred. When discontinuing chronically administered Metoprolol, particularly in patients with ischemic heart disease, gradually reduce the dosage over a period of 1 to 2 weeks and monitor the patient. If angina markedly worsens or acute coronary ischemia develops, promptly reinstate Metoprolol, and take appropriate measures for the management of unstable angina. Warn patients not to interrupt therapy without their physician's advice. *Heart failure*: Worsening cardiac failure may occur during up-titration of Metoprolol. If such symptoms occur, increase diuretics and restore clinical stability before advancing the dose of Metoprolol.

DRUG INTERACTIONS: ***Azelnidipine:*** The risk or severity of adverse effects can be increased when Azelnidipine is combined with 2-hydroxy-1,4- naphthoquinone, 2-mercaptobenzothiazole, Amorolfine and Amphotericin B. *Alfuzosin* may increase the hypotensive activities of Azelnidipe. *Amobarbital* The metabolism of Azelnidipine can be increased when combined with Amobarbital. ***Metoprolol***: *Catecholamine Depleting Drugs*: (e.g., reserpine, monoamine oxidase (MAO) inhibitors) may have an additive effect when given with beta-blocking agents. Observe patients treated with Metoprolol plus a catecholamine depletor for evidence of hypotension or marked bradycardia, which may produce vertigo, syncope, or postural hypotension. *CYP2D6 Inhibitors: S*uch as quinidine, fluoxetine, paroxetine, and propafenone increases in plasma concentration decrease the cardio selectivity of metoprolol. Monitor patients closely when the combination cannot be avoided. *Digitalis, Clonidine, and Calcium Channel Blockers (e.g diltiazem, and verapamil)*: slow atrioventricular conduction and decrease heart rate.

Concomitant use with beta-blockers can increase the risk of bradycardia. If clonidine and metoprolol are co-administered, withdraw the beta-blocker several days before the gradual withdrawal of clonidine because beta-blockers may exacerbate the rebound hypertension that can follow the withdrawal of clonidine. If replacing clonidine by beta-blocker therapy, delay the introduction of beta-blockers for several days after clonidine administration has stopped.

ADVERSE REACTIONS: ***Azelnidipine:*** Rash, itch, general malaise, loss of appetite, yellowness of skin and white eye, dizziness, light headedness, atrioventricular block, sinus arrest, bradycardia, hepatic function disorder with elevations of AST (GOT), ALT (GPT), γ-GTP, jaundice may occur. ***Metoprolol:*** Worsening angina or myocardial infraction, worsening heart failure, worsening AV block, hypertension, angina, tiredness, dizziness, depression, diarrhea, shortness of breath, rash, dizziness/vertigo, bradycardia, hypotension, stroke and death.

MARKETED BY:

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IN/ UNIAZ BETA 8 mg +25 mg & 8 mg+50 mg, 16 mg +25 mg & 16 mg+50 mg/MAY-2024/01/ABPI

(Additional information is available on request)