

## TOLOL H 50

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

Abbreviated Prescribing information for **TOLOL H 50** (Metoprolol Succinate Extended Release and Hydrochlorothiazide Tablets.)

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES:

**MECHANISM OF ACTION:** The mechanism of the antihypertensive effects of beta-adrenergic blockers 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. The mechanism of the antihypertensive effect of thiazide diuretics is unknown.

**INDICATIONS:** For the treatment of mild to moderate hypertension in adults.

**DOSAGE AND ADMINISTRATION:** As directed by physician.

**CONTRAINDICATION:** TOLOL H is contraindicated in patients with: Cardiogenic shock or decompensated heart failure, Sinus bradycardia, sick sinus syndrome, and greater than first-degree block unless a permanent pacemaker is in place, Anuria, Hypersensitivity to metoprolol succinate or hydrochlorothiazide or to other sulfonamide derived drugs.

**WARNINGS & PRECAUTIONS:** *Abrupt discontinuation:* of TOLOL H can lead to angina, myocardial infarction, or coronary ischemia—taper gradually over 1–2 weeks, *Heart failure:* may worsen during dose increases; stabilize the patient before continuing titration. *Bronchospasm:* risk exists; use with caution in bronchospastic disease and keep bronchodilators available. *Bradycardia* (e.g., sinus pause, AV block) may occur, especially with interacting drugs—monitor heart rate closely. Avoid *starting high doses:* before non-cardiac surgery due to risks of stroke, hypotension, and bradycardia. Beta-blockers may *mask hypoglycemia:* symptoms like tachycardia; dizziness and sweating may still be noticeable. *Electrolyte imbalances:* (e.g., hypokalemia, hyponatremia) and metabolic effects may occur due to hydrochlorothiazide. Risk of *acute renal failure* in patients with kidney disease, heart failure, or dehydration. Can *worsen peripheral vascular disease* and paradoxically raise BP in phaeochromocytoma—use alpha-blocker first. TOLOL H may trigger *thyroid storm, glaucoma, lupus exacerbation,* and reduce *epinephrine effectiveness* during anaphylaxis.

**DRUG INTERACTIONS:** *Catecholamine depletors* (e.g., reserpine, MAOIs) with metoprolol can cause additive *bradycardia or hypotension*—monitor closely. *CYP2D6 inhibitors* (e.g., fluoxetine, quinidine) can increase *metoprolol levels*; monitor for enhanced effects. *Digoxin, clonidine, and calcium channel blockers* may increase risk of *bradycardia*—special caution during withdrawal or switching. *Hydrochlorothiazide* may reduce the effect of *antidiabetics*, interact with *ion exchange resins*, and increase *lithium toxicity*. *NSAIDs* can blunt the *antihypertensive and diuretic effects* of hydrochlorothiazide.

**ADVERSE REACTIONS: Metoprolol:** *Central Nervous System:* Confusion, short-term memory loss, headache, somnolence, nightmares, insomnia, anxiety/nervousness, hallucinations, paresthesia, dizziness. *Cardiovascular:* Shortness of breath, bradycardia, cold extremities; arterial insufficiency (usually of the Raynaud type), palpitations, peripheral edema, syncope, chest pain. *Respiratory:* Dyspnea. *Gastrointestinal:* Diarrhea, nausea, dry mouth, gastric pain, constipation, flatulence, heartburn, hepatitis, vomiting. *Hypersensitivity Reactions:* Pruritus, rash. *Miscellaneous:* Musculoskeletal pain, arthralgia, blurred vision, decreased libido, male impotence, tinnitus, reversible alopecia, dry eyes, worsening of psoriasis, Peyronie's disease, sweating, photosensitivity, taste disturbance, depression.

**Hydrochlorothiazide:** *Body as a Whole:* Weakness. *Cardiovascular:* Orthostatic hypotension. *Digestive:* Pancreatitis, jaundice (intrahepatic cholestatic jaundice), sialadenitis, cramping, gastric irritation, anorexia. *Hematologic:* Aplastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia. *Hypersensitivity Reactions:* Anaphylactic reactions, necrotizing angiitis (vasculitis and cutaneous vasculitis), respiratory distress including pneumonitis and pulmonary edema, photosensitivity, fever, urticaria. *Metabolic:* Glycosuria. *Musculoskeletal:* Muscle spasm. *Nervous System/Psychiatric:* Vertigo, paresthesias, restlessness. *Renal:* Interstitial nephritis. *Skin:* Erythema multiforme including Stevens-Johnson syndrome, exfoliative dermatitis including toxic epidermal necrolysis. *Special Senses:* Transient blurred vision, xanthopsia.

**MARKETED BY:**



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(Additional information is available on request)