RITEBEAT IV

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

Abbreviated Prescribing information for **RITEBEAT IV** [Amiodarone hydrochloride I.P 50mg, sterile concentrate I.P. 3ml] [Please refer the complete prescribing information available at www.torrentpharma.com] **PHARMACOLOGICAL PROPERTIES**: Amiodarone is generally considered a class III antiarrhythmic drug. It exerts a noncompetitive antisympathetic action, negative chronotropic effect in nodal tissues, negative dromotropic, blocks myocardial potassium channels and slowing of conduction and prolongation of refractoriness. **INDICATION**: Ritebeat I.V. is indicated for: (1)Initiation of treatment and prophylaxis of frequently recurring ventricular fibrillation and hemodynamically unstable ventricular tachycardia in patients refractory to other therapy. (2) Used to treat patients with VT/VF who are unable to take oral medication. **DOSAGE AND ADMINISTRATION**: Ritebeat i.v. dose recommendations for first 24 hours are as followsz. Loading infusions first rapid: 150 mg over the first 10 minutes (15 mg/min), followed by slow: 360 mg over the next 6 hours (1 mg/min), maintenance infusion 540 mg over the remaining 18 hours (0.5 mg/min). Ritebeat I.V. must be delivered by a volumetric infusion pump. Whenever possible, be administered through a central venous catheter **CONTRAINDICATION:** Contraindicated in patients with known hypersensitivity to any of the components including iodine, in patients with cardiogenic shock, marked sinus bradycardia and second-or third-degree AV block unless a functioning pacemaker is available. **WARNINGS & PRECAUTIONS**: Hypotension, bradycardia and AV block, liver enzyme elevations, proarrhythmia, adult respiratory distress syndrome, optic neuritis, neonatal hypo- or hyperthyroidism in pregnant woman and corneal refractive laser surgery. **DRUG INTERACTIONS**: Drugs those inhibits cyp450, drugs metabolized by cyp3a4, p glycoprotein, loratadine, cimetidine, trazodone, grapefruit juice, cyclosporine, hmg-coa reductase inhibitors, cardiac glycosides, quinidine, procainamide, disopyramide, phenytoin, β-receptor blocking agents, calcium channel antagonists, warfarin, clopidogrel, rifampin, st. john's wort, fentanyl, dextromethorphan, cholestyramine, disopyramide, fluoroquinolones, macrolide antibiotics, and azoles. **ADVERSE REACTIONS:** Hypotension, asystole/cardiac arrest/electromechanical dissociation (EMD), cardiogenic shock, congestive heart failure, bradycardia, liver function test abnormalities, VT, and AV block, abnormal kidney function, atrial fibrillation, diarrhea, increased ALT, increased AST, lung edema, nodal arrhythmia, prolonged QT interval, respiratory disorder, shock, sinus bradycardia, Stevens-Johnson syndrome, thrombocytopenia, VF, vomiting, angioedema, hepatitis, acute pancreatitis, renal impairment, bronchospasm, possibly fatal respiratory disorders, bronchiolitis obliterans organizing pneumonia (possibly fatal), fever, dyspnea, cough, hemoptysis, wheezing, hypoxia, pulmonary infiltrates and/or mass, pleuritis, pseudotumor cerebri, syndrome of inappropriate antidiuretic hormone secretion (SIADH), thyroid nodules/thyroid cancer, toxic epidermal necrolysis (sometimes fatal), erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis, vasculitis, pruritus, anemia, pancytopenia, neutropenia, thrombocytopenia, agranulocytosis, granuloma, myopathy, hallucination, confusional state, disorientation, delirium, impotence and dry mouth also have been reported with amiodarone therapy.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

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(Additional information is available on request)