RITEBEAT

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

Abbreviated Prescribing information for **RITEBEAT** [Amiodarone hydrochloride I.P 100 /200mg tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Amiodarone HCl is a member of a class of antiarrhythmic drugs with predominantly Class III. The antiarrhythmic effect of amiodarone may be attributed to at least two major properties:1) A prolongation of the myocardial cell-action potential duration and refractory period. 2) Noncompetitive α- and β-adrenergic inhibition. **INDICATION**: Ritebeat is indicated only for the treatment of 1. Recurrent ventricular fibrillation. 2. Recurrent hemodynamically unstable ventricular tachycardia. **DOSAGE AND ADMINISTRATION**: **Ventricular Arrhythmias:** Loading dose (Daily): for 1 to 3 weeks - 800 to 1600 mg. Adjustment and maintenance dose (Daily): for approximately one month - 600 to 800 mg. Usual maintenance - 400 mg. **CONTRAINDICATION:** Contraindicated in patients with cardiogenic shock; severe sinus-node dysfunction, causing marked sinus bradycardia; second-or third-degree atrioventricular block; and when episodes of bradycardia have caused syncope (except when used in conjunction with a pacemaker and with a known hypersensitivity to the drug or to any of its components, including iodine.) **WARNINGS & PRECAUTIONS**: Hypersensitivity pneumonitis or interstitial/alveolar pneumonitis, abnormal liver enzymes, overt liver disease, arrhythmia exacerbation. caution should be exercised in patients with implanted defibrillators or pacemakers, corneal refractive laser surgery, neonatal hypo or hyperthyroidism in pregnant woman, neuritis, corneal microdeposits, photosensitivity, thyroid abnormalities and adult respiratory distress syndrome. **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:** Sinus arrest, anaphylactic/anaphylactoid reaction (including shock), angioedema, urticaria, eosinophilic pneumonia, hepatitis, cholestatic hepatitis, cirrhosis, pancreatitis, acute pancreatitis, renal impairment, renal insufficiency, acute renal failure, acute respiratory distress syndrome in the post-operative setting, bronchospasm, possibly fatal respiratory disorders (including distress, failure, arrest, and ARDS), bronchiolitis obliterans organizing pneumonia (possibly fatal), fever, dyspnea, cough, hemoptysis, wheezing, hypoxia, pleural effusion, pleuritis, pseudotumor cerebri, parkinsonian symptoms such as akinesia and bradykinesia (sometimes reversible with discontinuation of therapy), syndrome of inappropriate antidiuretic hormone secretion (SIADH), thyroid nodules/thyroid cancer, toxic epidermal necrolysis (sometimes fatal), erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis, bullous dermatitis, drug rash with eosinophilia and systemic symptoms (DRESS), eczema, skin cancer, vasculitis, pruritus, hemolytic anemia, aplastic anemia, pancytopenia, neutropenia, thrombocytopenia, agranulocytosis, granuloma, myopathy, muscle weakness, rhabdomyolysis, demyelinating polyneuropathy, hallucination, confusional state, disorientation, delirium, epididymitis, impotence and dry mouth also have been reported with amiodarone therapy.

MARKETED BY:

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IN/ RITEBEAT 100,200mg/Oct-2015/01/Abpi
(Additional information is available on request)