

PACERONE[®]

[Amiodarone HCl] Tablets

100mg 200mg
400mg



100mg



200mg



400mg

Product	Pkg	NDC#
PACERONE [®] Tablets 100mg	30 tablets/bottle	0245-0144-30
PACERONE [®] Tablets 100mg	100 tablets/ unit-dose carton	0245-0144-01
PACERONE [®] Tablets 200mg	60 tablets/bottle	0245-0147-60
PACERONE [®] Tablets 200mg	90 tablets/bottle	0245-0147-90
PACERONE [®] Tablets 200mg	500 tablets/bottle	0245-0147-15
PACERONE [®] Tablets 200mg	100 tablets/ unit-dose carton	0245-0147-01
PACERONE [®] Tablets 400mg	30 tablets/bottle	0245-0145-30
PACERONE [®] Tablets 400mg	100 tablets/ unit-dose carton	0245-0145-01

Important Safety Information

PACERONE[®] (Amiodarone HCl) Tablets are indicated only for the treatment of recurrent life-threatening VT-VF refractory to, or intolerant of, other agents. PACERONE[®] Tablets carry the potential for serious adverse reactions. Therefore, PACERONE[®] Tablets should be administered only by physicians experienced in the treatment of life-threatening arrhythmias and familiar with the risks and benefits of amiodarone therapy. Serious adverse reactions to amiodarone include: pulmonary toxicity (2%-7% in most studies, but as high as 10%-17% in some reports; fatal in about 10% of cases), liver function test abnormalities (4%-9%), hyperthyroidism (about 2%), hypothyroidism (2%-4% in most series, but as high as 8%-10% in some series), proarrhythmia (2%-5%), and optic neuropathy, in some cases leading to blindness. As is the case for other antiarrhythmic agents, there is no evidence from controlled trials that the use of amiodarone favorably affects survival. Because of the life-threatening nature of arrhythmias, potential interactions with prior therapy, and the potential exacerbation of the arrhythmia, initiation of therapy with PACERONE[®] Tablets should be carried out in the hospital. Please refer to full prescribing information for BOXED WARNING, including information related to the difficulties associated with dosage adjustment and discontinuation.

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