

PARTICULARS TO APPEAR WITHIN THE OUTER PACKAGING (CARTON)
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PRE-INFUSION CHECK-LIST

Important Instructions when using BRINAVESS

Prior to administration the prescriber is asked to determine eligibility of the patient through use of the supplied checklist. The checklist should be placed on the infusion container to be read by the healthcare professional who will administer BRINAVESS.

BRINAVESS should be administered in a monitored clinical setting appropriate for cardioversion by a well-qualified healthcare professional. Patients should be frequently monitored for the duration of the infusion and for at least 15 minutes after the completion of the infusion for signs and symptoms of a sudden decrease in blood pressure or heart rate.

Read carefully the Summary of Product Characteristics and the Health Care Professional Information Card prior to the administration of BRINAVESS

BRINAVESS must NOT be given to any patients with a “YES” response below:

Does the patient have heart failure class NYHA III or NYHA IV?	YES	NO
Has the patient presented with an acute coronary syndrome (including myocardial infarction) in the last 30 days?	YES	NO
Does the patient have severe aortic stenosis?	YES	NO
Does the patient have a systolic blood pressure < 100 mm Hg?	YES	NO
Does the patient have prolonged QT interval at baseline (uncorrected > 440 msec)?	YES	NO
Does the patient have severe bradycardia, sinus node dysfunction or second and third degree heart block, in the absence of a pacemaker?	YES	NO
Has the patient received an intravenous rhythm control antiarrhythmic drug (class I and/or class III) within 4 hours of the time when BRINAVESS will be infused?	YES	NO
Does the patient have hypersensitivity to the active substance or to any of the excipients?	YES	NO

Do NOT give other IV antiarrhythmic medicines (class I and/or class III) for at least 4 hours after infusion of BRINAVESS.

When giving BRINAVESS, follow these instructions:

- The patient should be adequately hydrated and haemodynamically optimised and adequately anticoagulated (if necessary) prior to administering BRINAVESS
- Observe the patient frequently and carefully for the entire duration of the infusion and for at least 15 minutes after completion of the infusion for:
 - Any signs or symptoms of a sudden decrease in blood pressure or heart rate, with or without symptomatic hypotension or bradycardia
 - Bradycardia
 - Hypotension
 - Unexpected ECG changes (see SmPC)If such signs develop, discontinue BRINAVESS immediately and provide appropriate medical management. Do not re-start BRINAVESS.
- Continue to monitor the patient for 2 hrs after the start of infusion and until clinical and ECG parameters have stabilised.