

Administration of PB2452: Loading Dose Infusion
Mandatory Documentation

LOADING DOSE:

Patients not on a CYP3A inhibitor will be infused:

- **6g (60 mls) over 4 hours (pump rate 15 mL/hr)**

Patients on a strong or moderate inhibitor will be infused:

- **12g (120 mls) over 6 hours (pump rate 20 mL/hr)**

Refer to Pharmacy Manual and Dosing schematic for additional guidance.

Reminders: confirm dose dispensing in EDC – to be completed as soon as possible after infusion
Infusion Site Assessments to be recorded on Vital Sign Assessment Worksheet

LOADING DOSE:

Loading infusion start date: ____/____/____

Start time: _____ am / pm End time: _____ am / pm

Dose: _____ g Infusion rate: _____ mL/ hr

Method of administration for loading dose:

IV Bag via infusion pump

Syringe via syringe pump

Other: Please specify: _____

Type of tubing used:

Filtered IV set

Vented IV set

Non-vented IV set

Gravity tubing

Other: _____

Length of Tubing used: _____ cm / inches

Was a post flush given? Yes No Unknown

Was this dose combined with the previous dose? Yes No

Was this dose combined with the next dose? Yes No

Total volume infused for this dose: _____

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Was dose adjusted from the planned dose: No Yes

If yes, reason dose was adjusted:

Adverse event: _____

Dosing error: _____

Physician's decision: _____

Other: _____

Was the dose / infusion interrupted? No Yes - Specify reason:

Adverse event: _____

Insufficient efficacy: _____

Dosing error: _____

Equipment failure: _____

Other: _____

Interruption stop time: _____ am/pm Re-start time: _____ am / pm

Total interruption duration: _____ mins

Was the full loading dose of PB2452 administered to the patient? Yes No

If no, estimated left over volume: _____ ml

Reason: _____

Addition Notes: _____

Loading Dose Source Documents Completed By:

_____/_____/_____
Printed Name and Qualification(s) Signature Date

PI SIGNATURE SECTION – Principal Investigator signature is required below to signify review:

_____/_____/_____
Printed Name Signature Date