

Administration of PB2452: Visit 2.0 – Bolus Dose
Mandatory Documentation

BOLUS DOSE:

Patients not on a CYP3A inhibitor will be infused:

- **6g (60 mls) over 10 minutes (pump rate 360 mL/hr)**

Patients on a strong or moderate CYP3A inhibitor will be infused:

- **12g (120 mls) over 10 minutes (pump rate 720 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

BOLUS DOSE:

Bolus infusion start date: ____/____/____

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

Dose: _____ g Infusion rate: _____ mL/ hr

Method of administration for bolus 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 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 bolus dose of PB2452 administered to the patient? Yes No

If no, estimated left over volume: _____ ml

Reason: _____

Addition Notes:

Bolus 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*