

**Administration of PB2452: Extended Dose
Mandatory Documentation**

If in the opinion of the treating clinician, extended reversal is needed based on signs or symptoms of ongoing hemorrhage or risk of re-bleeding, the maintenance infusion of PB2452 may be extended with an additional 6 g (60 mL) of PB2452 infused for 12 more hours or 12 g (120 mL) in subjects taking moderate or strong CYP3A inhibitors of PB2452 infused for 18 more hours

EXTENDED DOSE:

Reason for extended dose: _____

Patients not on a CYP3A inhibitor will be infused:

- **6g (60 mls) over 12 hours (pump rate 5 mL/hr)**

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

- **12g (120 mls) over 18 hours (pump rate 6.67 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

EXTENDED DOSE:

Extended infusion start date: ____/____/____

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

Dose: _____ g Infusion rate: _____ mL/ hr

Method of administration for extended 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: _____

Administration of PB2452: Extended Dose
Mandatory Documentation

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: _____

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 extended dose of PB2452 administered to the patient? Yes No

If no, estimated left over volume: _____ ml

Reason: _____

Administration of PB2452: Extended Dose
Mandatory Documentation

VITAL SIGNS	
Date completed: ____/____/____	Time completed: _____ am / pm
Blood pressure: _____ / _____ mmHg	Location: <input type="checkbox"/> Arm <input type="checkbox"/> Leg <input type="checkbox"/> Right <input type="checkbox"/> Left
Heart rate: _____ bpm	Respiratory rate: _____ breaths / min
Oral temperature: _____ <input type="checkbox"/> °F or <input type="checkbox"/> °C	Completed by (initials): _____

Reminder: Continue to assess for Adverse Events and Infusion Site reactions during the extended dosing

Addition Notes:

Extended Dose Source Documents Completed By:		
_____	_____	____/____/____
<i>Printed Name and Qualification(s)</i>	<i>Signature</i>	<i>Date</i>
<u>PI SIGNATURE SECTION</u> – Principal Investigator signature is required below to signify review:		
_____	_____	____/____/____
<i>Printed Name</i>	<i>Signature</i>	<i>Date</i>