PRODUCT COMPLAINT FORM

Glecaprevir(100mg)/Pibrentasvir(40mg) tablets

Product complaints refer to any suspected quality defect in the study drug or its package or labelling

SITE INFORMATION

Kirby Protocol Number: VHCRP1701 EDURACT Number: 2017-000694-37

To: Kirby Institute, VHCRP Fax No: +61 2 9385 9214 Email: smartc@kirby.unsw.edu.au

To: AbbVie Email: RD_PQC_QA@abbvie.com

Pages:_____ Date of report *(dd/mon/yyyy)*: ____/_____/_____

Principal Investigator's Name: _____ Reported By: _____

Site Phone Number: _____ Site Fax No: _____

STUDY DRUG DETAILS

1. Serial/lot number of drug product: _____ Expiry date (dd/mon/yyyy):): ____/ _____/ _____

2. Was the drug administered to the participant? ☐ Yes ☐ No
(if YES, complete questions 3-8; if NO proceed to question 9)

3. Subject ID Number: 1701-__ __ __ __ __-__ __ Initials: ___ ___-___ ___

4. Dose administered: 300/120 mg Glecaprevir/Pibrentasvir

5. Was administration performed per protocol? ☐ Yes ☐ No, please explain:_____

6. Was the participant/caregiver trained? ☐ Yes ☐ No, please explain:_____

7. Were there administration problems prior to this event? ☐ Yes, please explain:_____ ☐ No

8. Did interruption of study drug occur? ☐ Yes, please explain:_____ ☐ No

SITE STAFF SIGN-OFF

I verify that the information contained in this PRODUCT COMPLAINT FORM is accurate and compatible with the source documents.

Name (Please print): _____

Signature: _____

Date *(dd/mon/yyyy):* ____/ _____/ _____

KIRBY

Received date: _____ Received By: _____

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PRODUCT COMPLAINT DETAILS

9. Date of occurrence/onset *(dd/mon/yyyy)*: ____/_____/_____

10. Product complaint description:
Please provide a detailed description of the complaint including what the subject was doing when the complaint occurred

11. Is the complaint drug product available and quarantined? ☐ Yes ☐ No, please explain:_____

12. Can representative pictures be provided? ☐ Yes ☐ No
(if YES, please send via email)

13. Was the medication shipment damaged? ☐ Yes, please explain:_____ ☐ No

14. Number of units bottles/tablets affected:_____

15. Was the tamper evident seal intact when it arrived at the site? ☐ Yes ☐ No

16. Did the site personnel/participant notice any other unusual attributes with the bottle/packaging?

☐ Yes, please explain:_____ ☐ No

17. Was this complaint associated with an AE/SAE? ☐ Yes, please explain:_____ ☐ No