

# IMPAACT 2001

# Pharmacy Considerations

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# Presentation Overview

- Study Product
- Ordering, Shipment and Receipt
- Supply and Storage
- Dosing and Administration
- Accountability
- Final Disposition

# Study Product

- Study provided products:
  - Rifapentine (Priftin®) (RPT) film-coated tablets
    - Anti-Tuberculosis Agent
  - Isoniazid tablets
    - Anti-Tuberculosis Agent
- Non-study provided products:
  - Pyridoxine (Vitamin B<sub>6</sub>) tablets

# Ordering, Shipment and Receipt

- Study product will be ordered from the Clinical Research Products Management Center (CRPMC) by the site pharmacist
- After protocol registration, the site pharmacist(s) will receive ordering instructions from the CRPMC and place an order using the Study Product Request Form, which can be found in the Pharmacy Guidelines
- After confirmation of protocol registration and receipt of order at the CRPMC, study product will be packaged and shipped to the site pharmacist

# Study Product: How Supplied and Storage

- Rifapentine (RPT) (Priftin®)
  - 150 mg tablets
  - 24 tablets per carton
  - Store at 25°C (77°F); excursions permitted from 15°-30° C (59°-86°F)
  - Protect from excessive heat and humidity
- Isoniazid
  - 300 mg tablets
  - Bottles of 30's
  - Do not store above 30°C; excursions permitted from 15°-30° C (59°-86°F)

# Study Product: Dosing and Administration

Participants in both Cohorts will receive the following regimen:

- Rifapentine (RPT) 900 mg (6 x 150 mg tablets) by mouth, under directly observed therapy, with food once-weekly for 12 weeks
  - RPT tablets should be swallowed whole and not chewed, broken or crushed; 30 minutes after food intake
- Isoniazid (INH) 900 mg (3 x 300 mg tablets) by mouth, under directly observed therapy, with food once-weekly for 12 weeks
  - INH tablets should be swallowed whole and not chewed, broken or crushed; 30 minutes after food intake
- Pyridoxine 25-100 mg by mouth once-weekly in conjunction with RPT + INH
  - Pyridoxine can be given whole or crushed
  - Exact dose to be determined by site clinician, based on the current local, national, or international dosing guidelines.

# Study Product: Dosing and Administration cont'd

- Dose adjustments for RPT and INH may be warranted based upon the results of the interim analysis

(Please review section 10.3.2 of the protocol for detailed dose adjustment information)

# Study Product Accountability

- Accountability records must be kept by the Pharmacist
  - Refer to section on “*Accountability*” under the *Study Products Management Responsibilities* section in the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trial Networks* manual.



# Study Product Final Disposition

- At study completion or termination:
  - U.S. Sites: All unused study product must be returned to the CRPMC.
  - Non-U.S. Sites: The site pharmacist must follow the instructions in the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks* for the destruction of unused study products.