Use of Injectable CAB/RPV LA as Replacement ART in Virally Suppressed Adults

August 2022

| Table 2: Optional Lead-in, Initiation, and Maintenance for MONTHLY (every 4 weeks) CAB/RPV LA Dosing [a] | | | |
|--|--------------------------------|---|--|
| Timing | Dosing and Administration | Comments | |
| Optional oral lead-in: | CAB 30 mg/RPV 25 mg once daily | Oral medication lead-in | |
| Therapy Initiation: | by mouth with a meal x 4 weeks | | |
| Week 0 (aka month 0) | | | |
| Week 4 (aka month 1) | CAB 600 mg (3 mL)/RPV 900 mg | Initiation dose: Administer on last day of oral | |
| | (3 mL) IM injection | lead-in or prior suppressive ART regimen | |
| Week 8 (aka month 2) and every | CAB 400 mg (2 mL)/RPV 600 mg | Maintenance dose: Administer within 7 days | |
| 4 weeks (aka every 1 month) | (2 mL) IM injection | before or after scheduled date (see Managing | |
| thereafter | | Missed or Delayed Injections) | |

Abbreviations: aka, also known as; ART, antiretroviral therapy; CAB, cabotegravir (brand name Vocabria); CAB/RPV LA, injectable long-acting cabotegravir/rilpivirine (brand name Cabenuva); IM, intramuscular; RPV, rilpivirine (brand name Edurant).

Note:

a. FDA. Cabenuva (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension), copackaged for intramuscular use. 2021 Jan. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212888s000lbl.pdf [accessed 2021 Mar 08]

| Table 3: Optional Lead-in, Initiation, and Maintenance for BIMONTHLY (every 8 weeks) CAB/RPV LA Dosing [a,b] | | | |
|--|---|---|--|
| Timing | Dosing and Administration | Comments | |
| Optional oral lead-in: Therapy initiation: Week 0 (aka month 0) | CAB 30 mg/RPV 25 mg once daily by mouth with a meal x 4 weeks | Oral medication lead-in | |
| Week 4 (aka month 1) | CAB 600 mg (3 mL)/RPV 900 mg (3 mL) IM injection | Initiation dose: Administer on last day of oral lead-in or prior suppressive ART regimen | |
| Week 8 (aka month 2) | CAB 600 mg (3 mL)/RPV 900 mg (3 mL) IM injection | Maintenance dose: Administer within 7 days before or after scheduled date (see Managing Missed or Delayed Injections) | |
| Week 16 (aka month 4) and every 8 weeks (aka every 2 months) | CAB 600 mg (3 mL)/RPV 900 mg (3 mL) IM injection | Maintenance dose: Administer within 7 days before or after scheduled date (see | |
| thereafter | (3 mz) ivi injection | Managing Missed or Delayed Injections) | |

Abbreviations: aka, also known as; ART, antiretroviral therapy; CAB, cabotegravir (brand name Vocabria); CAB/RPV LA, injectable long-acting cabotegravir/rilpivirine (brand name Cabenuva); IM, intramuscular; RPV, rilpivirine (brand name Edurant).

Notes:

- a. ViiV Healthcare. ViiV Healthcare announces US FDA approval of cabenuva (cabotegravir, rilpivirine) for use every two months, expanding the label of the first and only complete long-acting HIV treatment. 2022 https://viivhealthcare.com/hiv-news-and-media/news/press-releases/2022/january/viiv-healthcare-announces-fda-approval-of-cabenuva-for-use-every-two-months/ [accessed 2022 Feb 9]
- b. FDA. Cabenuva (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension), copackaged for intramuscular use. 2021 Jan. https://www.accessdata.fda.gov/drugsatfda docs/label/2021/212888s000lbl.pdf [accessed 2021 Mar 8]