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CABENUVA
CABOTEGRAVIR LONG-ACTING PLUS RILPIVIRINE LONG-ACTING
LIFELONG DAILY HIV THERAPY CAN BE CHALLENGING FOR SOME PLHIV

Fear of disclosure⁴⁻⁶
Stigma and inadvertent disclosure of HIV status remain concerns for many PLHIV

Daily reminder of HIV²
Psychological challenges can match physical manifestations

Adherence anxiety²
Daily medication can be restrictive and cause adherence anxiety

Dose skipping⁴
Patients have reported skipping or delaying doses to prevent inadvertent disclosure of HIV status

Positive Perspectives Study⁵

The largest proportion of respondents ranked ‘longer-lasting medicine so I don’t have to take it every day’ as their highest priority

DHHS AND IAS-USA GUIDELINES: CABENUVA STRONGLY RECOMMENDED FOR VIROLOGICALLY SUPPRESSED PATIENTS WITH HIV-1

DHHS Guidelines Now Recommend: CAB/RPV LA (AI)*

<table>
<thead>
<tr>
<th>Strength of Recommendation</th>
<th>=</th>
<th>Strong recommendation for the statement (A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Evidence</td>
<td>=</td>
<td>≥1 randomized trials with clinical outcomes (I)</td>
</tr>
</tbody>
</table>

IAS-USA Guidelines Now Recommend: CAB/RPV LA (AIa)**

<table>
<thead>
<tr>
<th>Strength of Recommendation</th>
<th>=</th>
<th>Strong panel support (A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Evidence</td>
<td>=</td>
<td>≥1 RCT published in peer-reviewed literature (Ia)</td>
</tr>
</tbody>
</table>

*Strength of Recommendation for the Statement: A=Strong; B=Moderate; C=Optional. Quality of Evidence: I= ≥1 randomized trials with clinical outcomes; II= ≥1 well designed, non-randomized trials or observational cohort studies with long-term clinical outcomes; III=expert opinion.

**Strength of Recommendation: A=Strong; B=Moderate; C=Limited or weak. Quality of Evidence: Ia=Evidence from ≥1 RCTs published in the peer-reviewed literature; Ib=Evidence from ≥1 RCTs presented in abstract form at peer-reviewed scientific meetings; Iib= Evidence from cohort or case-control studies published in the peer-reviewed literature; IIb = Evidence from cohort or case-control studies presented in abstract form at peer-reviewed scientific meetings; III=Based on the panel’s analysis of the available evidence.

CAB=cabotegravir; DHHS=Department of Health and Human Services; IAS=International Antiviral Society; LA=long-acting; RCT=randomized controlled trial; RPV=rilpivirine.


CABENUVA INDICATION

US FDA Prescribing Information:

CABENUVA (CAB + RPV LA), co-packaged for IM use

Indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current ARV regimen in those who are virologically suppressed* on a stable ARV regimen with no history of treatment failure and with no known or suspected resistance to either CAB or RPV.

*Defined as HIV-1 RNA <50 copies/mL

Study evaluating the efficacy, safety, and tolerability of switching to long-acting cabotegravir plus long-acting rilpivirine from current antiretroviral regimen in virologically suppressed HIV-1-infected adults.

First Long-Acting HIV Injectable Regimen (FLAIR)

Study evaluating the efficacy, safety, and tolerability of switching to long-acting cabotegravir plus long-acting rilpivirine from current antiretroviral regimen in virologically suppressed HIV-1-infected adults.
POOLED VIROLOGIC SNAPSHOT OUTCOMES AT WEEK 48 (ITT-E POPULATION): NONINFERIORITY ACHIEVED FOR PRIMARY AND SECONDARY ENDPOINTS\textsuperscript{1,2}

### Virologic outcomes

- **Primary endpoint:**
  - LA noninferior to Current ART (≥50 copies/mL) at Week 48

- **Key secondary endpoint:**
  - LA noninferior to Current ART (<50 copies/mL) at Week 48

---

CAB LA + RPV LA is noninferior to current ART for virologic outcomes at Week 48

\textsuperscript{a}Difference \(-\) (proportion given CAB LA + RPV LA) \(-\) (proportion given current ART).

\textsuperscript{b}Based on CMH stratified analysis adjusting to 10 strata.

POOLED OVERALL SUMMARY OF AES EXCLUDING ISRS DURING THE MAINTENANCE PHASE (POOLED SAFETY POPULATION)¹

<table>
<thead>
<tr>
<th></th>
<th>CAB LA + RPV LA IM Q4W (n = 591)</th>
<th>Current ART³ (n = 591)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any AE</td>
<td>506 (86)</td>
<td>444 (75)</td>
</tr>
<tr>
<td>Any Grade ≥3 AE</td>
<td>44 (7)</td>
<td>35 (6)</td>
</tr>
<tr>
<td>Any AE leading to withdrawal</td>
<td>17 (3)</td>
<td>9 (2)</td>
</tr>
<tr>
<td>Any SAE</td>
<td>24 (4)</td>
<td>25 (4)</td>
</tr>
<tr>
<td>Any fatal SAE</td>
<td>0</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Any drug-related AE</td>
<td>165 (28)</td>
<td>35 (6)</td>
</tr>
<tr>
<td>Any drug-related Grade ≥3 AE</td>
<td>8 (1)</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Common AEs (≥10% in either arm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>108 (18)</td>
<td>88 (15)</td>
</tr>
<tr>
<td>Headache</td>
<td>71 (12)</td>
<td>38 (6)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>66 (11)</td>
<td>52 (9)</td>
</tr>
</tbody>
</table>

Most AEs were Grade 1 or 2 and mild-to-moderate in severity (92% and 92%, respectively).

There was no pattern of events leading to treatment discontinuation, and <2% of patients on CAB + RPV LA withdrew due to ISRs or intolerability.

Current ART refers to ABC/DTG/3TC in FLAIR.

Notes: One fatal event: 1 death due to methamphetamine overdose and unrelated to study treatment was reported for the current ART group, and no deaths were reported in the CAB LA + RPV LA treatment group.


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ISRS WERE COMMON WITH CAB + RPV LA, THOUGH MOST WERE MILD AND INCIDENCE DECLINED OVER TIME

The majority of participants (55%) reported ≤3 injection pain events to 48 weeks. 85% of CAB + RPV LA participants rated pain as ‘totally/very acceptable’ at Week 48, as assessed by PIN.

<table>
<thead>
<tr>
<th>Event</th>
<th>CAB + RPV LA (N = 591)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants receiving injections, n</td>
<td>581</td>
</tr>
<tr>
<td>Injections given, n (%)</td>
<td>14,682</td>
</tr>
<tr>
<td>ISR events</td>
<td>3663 (24.9)</td>
</tr>
<tr>
<td>Pain</td>
<td>3087 (21.0)</td>
</tr>
<tr>
<td>Nodule</td>
<td>140 (1.0)</td>
</tr>
<tr>
<td>Induration</td>
<td>136 (0.9)</td>
</tr>
<tr>
<td>Swelling</td>
<td>86 (0.6)</td>
</tr>
<tr>
<td>Grade 3 ISR pain</td>
<td>32 (0.2)</td>
</tr>
<tr>
<td>Median duration of ISRs, days</td>
<td>3</td>
</tr>
<tr>
<td>Participants with ISR leading to withdrawal, n (%)</td>
<td>6 (1)</td>
</tr>
</tbody>
</table>

~25% of injections had ISR events, the majority (99%) of ISRs were Grade 1–2, median duration of 3 days and resulted in few discontinuations (<1%).

*Bars represent incidence of onset ISRs relative to the most recent LA injection visit. ISR, injection site reaction

POOLED ATLAS AND FLAIR: CAB + RPV LA WAS PREFERRED OVER DAILY ORAL ART\textsuperscript{1-3}

For the past 44 weeks you have received long-acting injectable HIV medication every month. Today we would like you to compare your experience on the long-acting injections with the oral medication you received prior to entering the study.

Which therapy do you prefer?

98% of responding participants from ATLAS + FLAIR preferred CAB + RPV LA over CAR at Week 48

\textsuperscript{*}In the overall ITT population, 88% (523/591) preferred the LA regimen over previous oral therapy, 10% (59/591) did not respond to the question, and 9/591 (2%) preferred daily oral ART

**CAB + RPV MONTHLY DOSING SCHEDULE: ORAL LEAD-IN AND IM INJECTIONS**

Patients may receive **CABENUVA** up to 7 days before or after the target date of the monthly injection.\(^1\)

**Oral Lead-in**  
(Minimum 28 days)
- **VOCABRIA (CAB) tablet**  
  Daily oral dose (30 mg)
- **EDURANT (RPV) tablet**  
  Daily oral dose (25 mg) taken with a meal

**CABENUVA Initiation Dose**
- **CAB LA**  
  Single IM injection (600 mg, 3 mL)
- **RPV LA**  
  Single IM injection (900 mg, 3 mL)

**CABENUVA Continuation Phase**
- **CAB LA**  
  Monthly IM injection (400 mg, 2 mL)
- **RPV LA**  
  Monthly IM injection (600 mg, 2 mL)

- Initiate injections on the final day of the oral lead-in
- Administer CAB LA and RPV LA at separate gluteal injection sites during the same visit

*Oral lead-in is used to assess the tolerability of VOCABRIA (CAB) and EDURANT (RPV) prior to the administration of CABENUVA (CAB + RPV LA)

DOSE INITIATION AND THE +/- 7 DAY DOSING WINDOW

Choose a ‘target date’ for injections

/ Injections should be given on the same date of the month

/ Consider 1\textsuperscript{st}–28\textsuperscript{th} of each month (not all months have equal days)

 +/- 7 day dosing window

/ Injections can be given up to 7 days before OR 7 days after the target date*

/ Patients should return to their target date (or as close as possible) the following injection

*Remain as close to the target date as possible


Example target treatment date of 15\textsuperscript{th}:

<table>
<thead>
<tr>
<th>Sun</th>
<th>Mon</th>
<th>Tue</th>
<th>Wed</th>
<th>Thu</th>
<th>Fri</th>
<th>Sat</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>5</td>
<td>6</td>
<td>7</td>
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<td>26</td>
<td>27</td>
<td>28</td>
<td>29</td>
<td>30</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Target Treatment Date

CABENUVA Dosing Window
**PACKAGING: CAB AND RPV FORMULATIONS**

**Oral Lead-in Components**

<table>
<thead>
<tr>
<th>CAB¹</th>
<th>RPV²</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 mg tablet for oral use</td>
<td>25 mg tablet for oral use</td>
</tr>
</tbody>
</table>

**CABENUVA is available** as an extended-release IM injection in single-dose copackaged kits.

<table>
<thead>
<tr>
<th>CAB LA¹</th>
<th>RPV LA²</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg/mL extended-release suspension for IM injection</td>
<td>300 mg/mL extended-release suspension for IM injection</td>
</tr>
</tbody>
</table>

**CABENUVA (CAB + RPV LA) dosing kit¹**

- **Initiation dose pack**
  - CAB 600 mg/3 mL
  - RPV 900 mg/3 mL

- **Continuation dose pack**
  - CAB 400 mg/2 mL
  - RPV 600 mg/2 mL

Each kit contains:
- 2 syringes, 2 syringe labels, 2 vial adapters, 2 needles for IM injection (23-gauge, 1½ inch)

**Store CABENUVA in the refrigerator** at 2° to 8°C (36° to 46°F) in the original carton until ready to use. Both kits are approximately 5.5 in. X 6 in.

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