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FOR REACTIVE USE ONLY

CABENUVA

CABOTEGRAVIR LONG-ACTING PLUS RILPIVIRINE LONG-ACTING

LIFELONG DAILY HIV THERAPY CAN BE CHALLENGING FOR SOME PLHIV

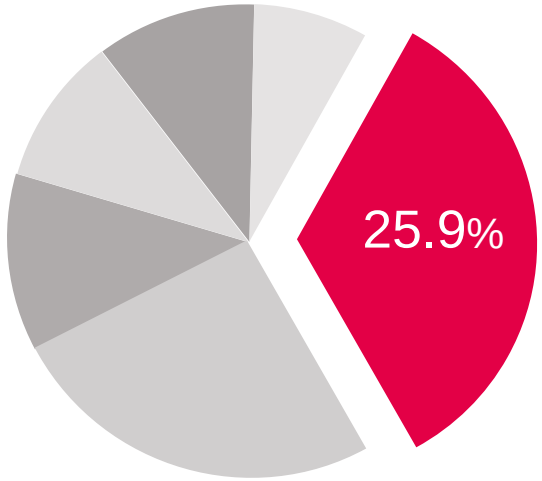
Fear of disclosure[1–3]
Stigma and inadvertent disclosure of HIV status remain concerns for many PLHIV

Daily reminder of HIV[2]
Psychological challenges can match physical manifestations

Adherence anxiety[2]
Daily medication can be restrictive and cause adherence anxiety

Dose skipping[4]
Patients have reported skipping or delaying doses to prevent inadvertent disclosure of HIV status

Positive Perspectives Study[5]



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

Positive Perspectives Study 2019 (N=2389)†

*PLHIV who ranked each attribute as either the first or second most important was: ‘reduced long-term impact on my body’ (46.7%); ‘longer-lasting medicine so I don’t have to take it every day’ (43.1%); ‘fewer side effects’ (40.5%); ‘less HIV medicine each day but just as effective’ (25.4%); less chance of affecting other medicines/drugs/pills I take’ (21.6%); ‘no food restrictions or requirements’ (14.0%); and ‘smaller pills’ (8.7%)
†Participants were enrolled from Europe (n=1119), North America (n=520), South Africa (n=179), Australia (n=120), Japan (n=75), Mexico (n=63), Brazil (n=58), Taiwan (n=55), Argentina (n=50), Chile (n=50), China (n=50), and South Korea (n=50)

- **An alternative form of ART administration may be beneficial to PLHIV who experience challenges associated with daily oral ART.**
- **Long-lasting treatment, requiring less frequent dosing, is one of the most important unmet needs for PLHIV.**

References: 1. Changing Perceptions: Talking About HIV and Attitude. Positive Voices Survey, 2018. 2. Young B, et al. IDWeek 2019. Poster 1329. 3. Katz IT, et al. *J Int AIDS Soc.* 2013;16 (Suppl 2):18640. 4. Muessig KE, et al. *AIDS Patient Care STDS.* 2015;29:606–16. 5. de los Rios P, et al. *Popul Med.* 2020;2:23.

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DHHS AND iAS-USA GUiDELiNES: CABENUVA STRONGLY RECOMMENDED FOR ViROLOGiCALLY SUPPRESSED PATiENTS WiTH HiV-1

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

Strength of Recommendation	=	Strong recommendation for the statement (A)
Quality of Evidence	=	≥1 randomized trials with clinical outcomes (I)

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

Strength of Recommendation	=	Strong panel support (A)
Quality of Evidence	=	≥1 RCT published in peer-reviewed literature (Ia)

*__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; IIa=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.

DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. US Department of Health and Human Services. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultARV_GL_ID_2021_CabRpv.pdf. Updated February 24, 2021. Accessed March 25, 2021.
Saag MS, et al. *JAMA*. 2020;324(16):1651-1669.

CABENUVA INDICATION

US FDA Prescribing Information:

CABENUVA (CAB + RPV LA), co-packaged for IM use[1]

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

References: 1. ViiV Healthcare. Cabenuva [prescribing information]. 2021.

Antiretroviral Therapy as Long-Acting Suppression (ATLAS)

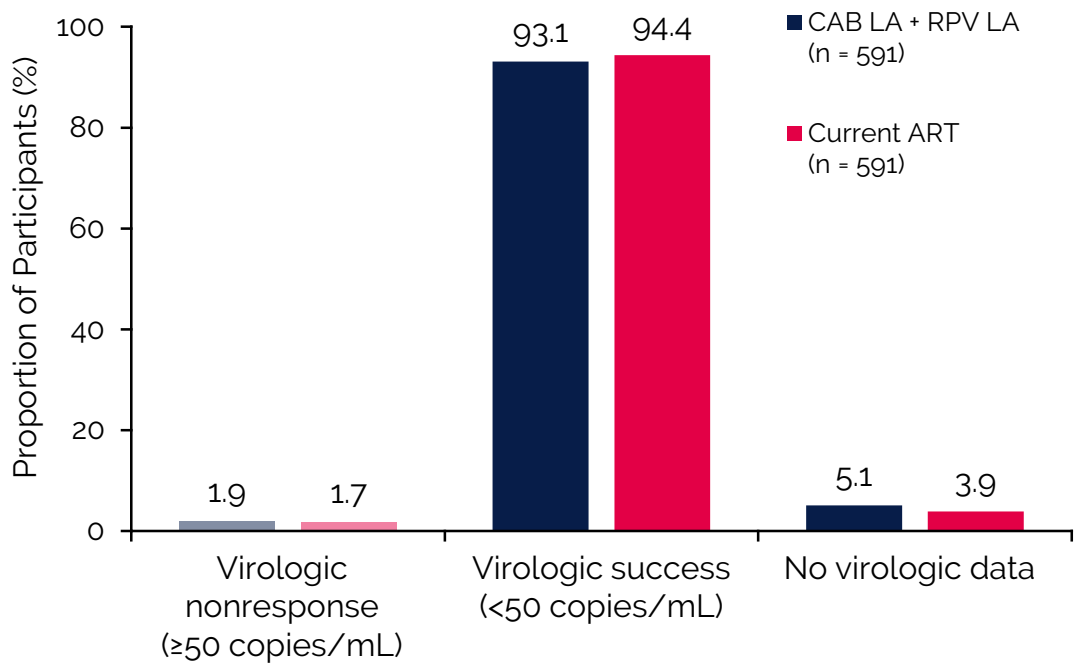
Study evaluating the efficacy, safety, and tolerability of switching to long-acting cabotegravir plus long-acting rilpivirine from current antiretroviral regimen **in virologically suppressed HIV-1-infected adults**

First Long-Acting HIV Injectable Regimen (FLAIR)

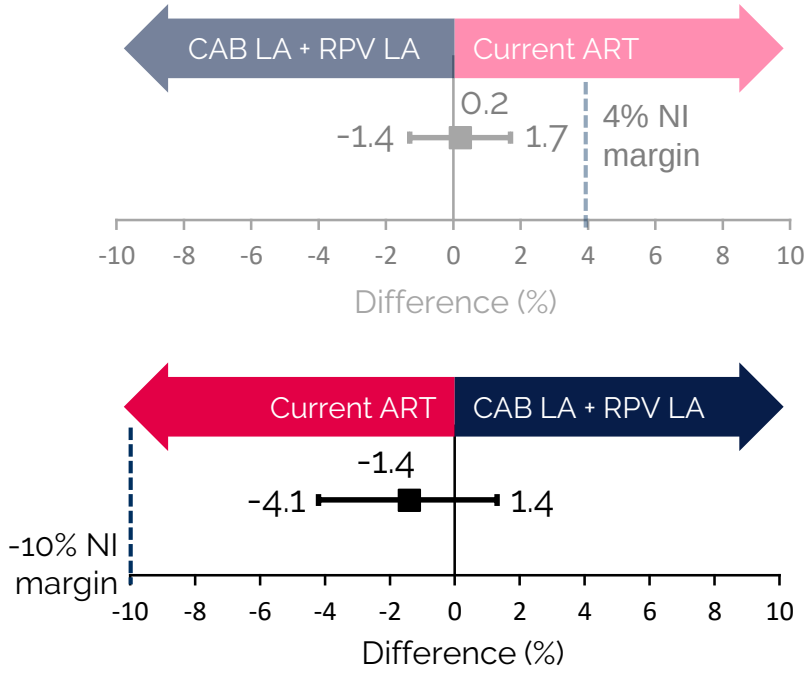
Study evaluating the efficacy, safety, and tolerability of switching to long-acting cabotegravir plus long-acting rilpivirine from current antiretroviral regimen **in virologically suppressed HIV-1-infected adults**

POOLED VIROLOGIC SNAPSHOT OUTCOMES AT WEEK 48 (ITT-E POPULATION): NONINFERIORITY ACHIEVED FOR PRIMARY AND SECONDARY ENDPOINTS[1,2]

Virologic outcomes



Adjusted treatment difference (95% CI)[a,b]



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

[a]Difference =(proportion given CAB LA + RPV LA) – (proportion given current ART).
[b]Based on CMH stratified analysis adjusting to 10 strata.

References: 1. ViiV Healthcare. *Integrated Summary of Efficacy [data on file].* 2019. 2. Rizzardini G, et al. *J Acquir Immune Defic Syndr.* 2020;85(4):498-506.

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

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

- 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

[a]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

References: 1. Rizzardini G, et al. *J Acquir Immune Defic Syndr.* 2020;85(4):498-506

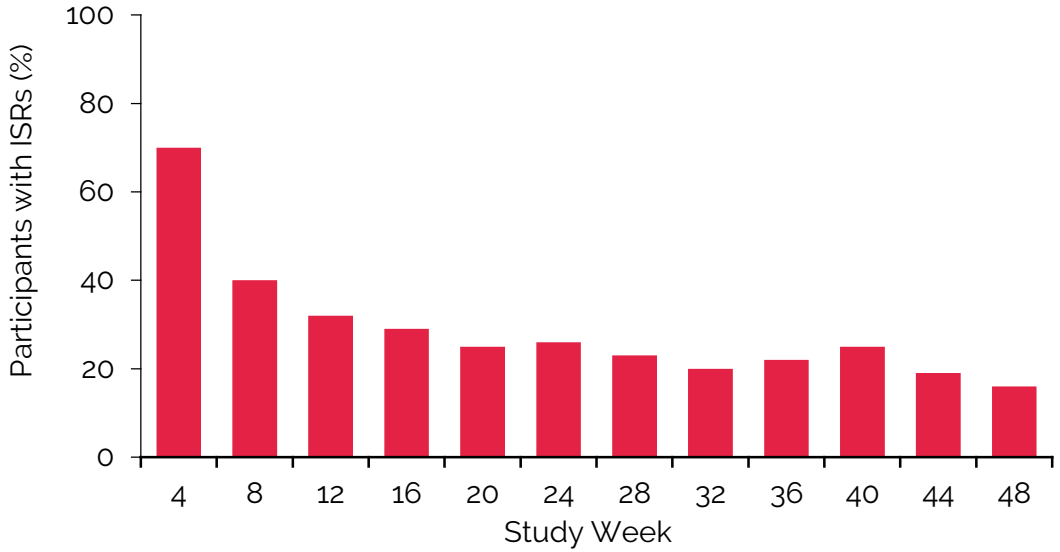
ISRS WERE COMMON WITH CAB + RPV LA, THOUGH MOST WERE MILD AND INCIDENCE DECLINED OVER TIME

The majority of participants (55%) reported ≤3 injection pain events to 48 weeks[1]

85% of CAB + RPV LA **participants rated pain as 'totally/very acceptable'** at Week 48,* as assessed by PIN[1]

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

ISR Incidence by Week*



~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%)[2]

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

References: 1. Teichner P, et al.. IDWeek; October 3, 2019, 2019; Washington, DC. 2. Overton ET, et al. Presented at 10th IAS Conference on HIV Science 2019; Mexico City, Mexico.

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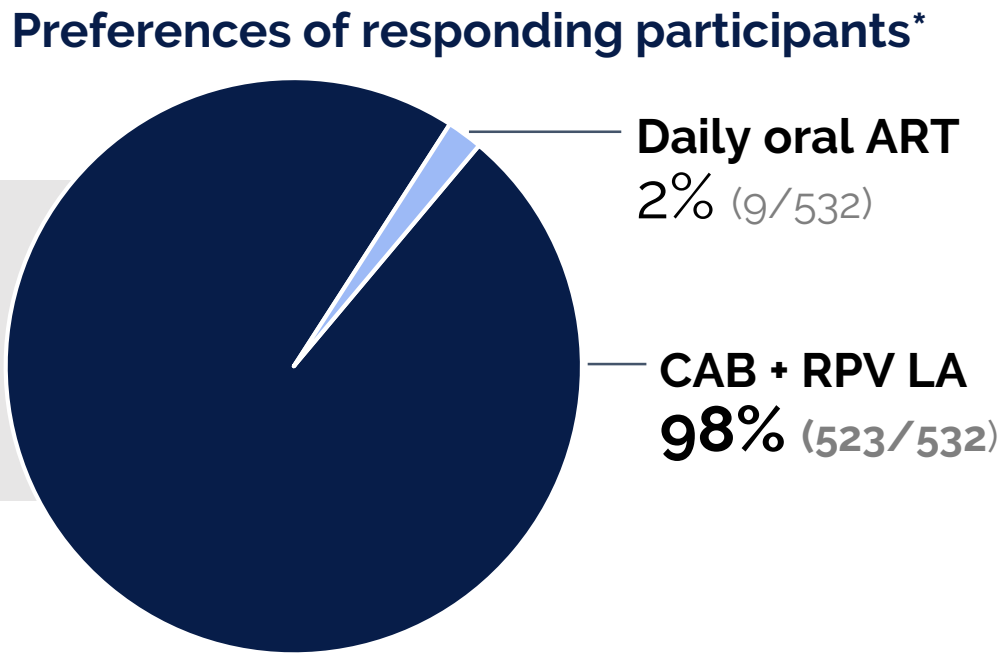
POOLED ATLAS AND FLAIR: CAB + RPV LA WAS PREFERRED OVER DAILY ORAL ART[1-3]

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

*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

References: 1. Swindells S, et al. Presentation presented at 26th CROI; March 4-7, 2019; Seattle, WA. 2. Orkin C, et al. Presentation presented at 26th CROI; March 4-7, 2019; Seattle, WA. 3. Murray M, et al. *AIDS Behav.* 2020;24(12):3533-3544.

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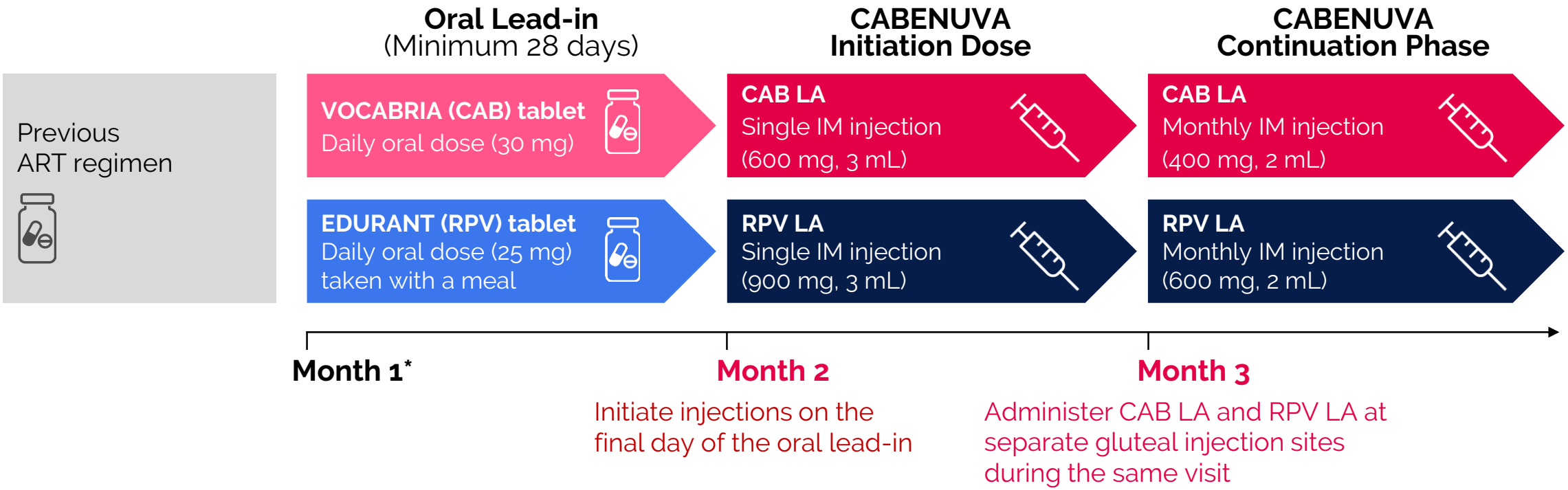
CAB + RPV MONTHLY DOSING SCHEDULE: ORAL LEAD-IN AND IM INJECTIONS

Patients may receive **CABENUVA** up to 7 days before or after the target date of the monthly injection.[1]



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

References: 1. ViiV Healthcare. Cabenuva [prescribing information]. 2021.

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DOSE INITIATION AND THE +/- 7 DAY DOSING WINDOW[1]

Choose a 'target date' for injections

- Injections should be given on the same date of the month
- Consider 1st–28th 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

References: 1. ViiV Healthcare. Cabenuva [prescribing information]. 2021.

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Example target treatment date of 15th:

Sun	Mon	Tue	Wed	Thu	Fri	Sat
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	**15**	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

Target Treatment Date

CABENUVA Dosing Window

PACKAGING: CAB AND RPV FORMULATIONS

Oral Lead-in Components

CAB[1]

30 mg tablet for oral use

RPV[2]

25 mg tablet for oral use

CABENUVA is available as an extended-release IM injection in single-dose copackaged kits.[1]

CAB LA[1]

200 mg/mL extended-release suspension for IM injection

RPV LA[2]

300 mg/mL extended-release suspension for IM injection

CABENUVA (CAB + RPV LA) dosing kit[1]

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.

References: 1. ViiV Healthcare. Cabenuva [prescribing information]. 2021. 2. Janssen Products, LP, Edurant [prescribing information]. 2021.

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