

Use of *Cabenuva* in Patients with Buttock Implants, Dermal Fillers, or Gluteal Fat Grafting (Brazilian Butt Lift)

Summary

- There is no exclusion on the use of *Cabenuva* (long-acting cabotegravir and rilpivirine [CAB + RPV LA]) in patients with buttock implants, dermal fillers, or who have had gluteal fat grafting (Brazilian butt lift [BBL]).¹
- Clinicians should assess the anatomical position of the implants or fillers and use their judgement to determine whether the CAB + RPV LA is appropriate for the patient.²
- CAB + RPV LA is approved for gluteal intramuscular injection only.¹ Pharmacokinetic (PK) data is available for thigh (*vastus lateralis*) administration.³
- Important Safety Information can be found in the <u>Prescribing Information</u> and can also be accessed from Our HIV Medicines.

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USE IN PATIENTS WITH BUTTOCK IMPLANTS, DERMAL FILLERS, OR GLUTEAL FAT GRAFTING (BBL)

During phase 3 clinical trials, patients were excluded if they had "any condition which, in the opinion of the investigator, may interfere with the absorption, distribution, metabolism or excretion of the study drugs or render the participant unable to receive study medication."

Clinicians should assess the anatomical position of the implants or dermal fillers and use their judgement to determine whether the CAB + RPV LA is appropriate for the patient.²

There is no exclusion on the use of CAB + RPV LA in patients with buttock implants, fillers, or who have had gluteal fat grafting (BBL). Clinicians should assess the anatomical position of the implants or fillers and use their judgement to determine whether the CAB + RPV LA is appropriate for the patient.

ATLAS-2M THIGH PK STUDY

CAB + RPV LA is approved for gluteal intramuscular injection only. PK data is available for thigh (vastus lateralis) administration.

For further information on the Phase 3 ATLAS-2M study, please click <u>here</u>. For further information on the PK thigh substudy, please click <u>here</u>.

The PK, safety, and efficacy of CAB + RPV LA, administered every-4-weeks (Q4W) or every-8-weeks (Q8W) following short-term repeat intramuscular (IM) thigh administration was evaluated in an optional ATLAS-2M sub-study.³

The substudy demonstrated CAB and RPV PK parameters following 16 weeks of thigh injections were similar to those after gluteal administration, with no clinically significant differences observed.³

Across the Q4W and Q8W arms, most ISRs were Grade 1 or 2 (93–96%). The median duration of ISRs was 3–3.5 days. One participant withdrew due to injection site pain.

Virologic suppression was observed across both arms (Q8W, 94.4% [n = 51/54]; Q4W, 95.3% [n = 61/64]) at sub-study Week 16.3 There were no cases of confirmed virologic failure and no patient had plasma HIV-1 RNA ≥ 50 during the sub-study. Three participants had no virologic data (discontinuation due to AE [Q8W, n = 1] and discontinuation due to other reasons [Q8W, n = 2; Q4W, n = 3]).

Overall, 30% of participants preferred thigh injections with the most common reasons including convenience/easy access (Q8W/Q4W, 71%); less bothered by pain following injection (Q8W, 65%; Q4W, 59%); less bothered by pain during injection (Q8W, 47%; Q4W, 65%).³

These results support short-term CAB + RPV LA lateral thigh administration within an established gluteal regimen.³

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This information is not intended to offer recommendations for using this product in a manner inconsistent with its approved labeling. Please consult the Prescribing Information. For ViiV Healthcare to monitor the safety of our products, we encourage healthcare professionals to report adverse events or suspected overdoses to the company at 877-844-8872.

Selection of references follows principles of evidence-based medicine and, therefore, references may not be all inclusive.



REFERENCES

- 1. ViiV Healthcare. Global Data Sheet for Cabotegravir (treatment). Version 11. July 16, 2024.
- 2. Patel P, Teichner P, Elliot E, et al. Practical dosing guidance for the management of clinician-administered injections of long-acting cabotegravir and rilpivirine. *Ther Adv Infect Dis.* 2023;10:20499361231214626. doi:http://dx.doi.org/10.1177/20499361231214626.
- 3. Felizarta F, et al. Thigh Injections of Cabotegravir+Rilpivirine in Virally Suppressed Adults with HIV-1. Presented at the 30th Conference on Retroviruses and Opportunistic Infections (CROI), February 19-22, 2023, Seattle, Washington. TBD.
- 4. Data on File. ATLAS (Study 201585).
- 5. Data on File. ATLAS-2M (Study 207966).
- 6. Data on File. SOLAR (Study 213500).
- 7. Data on File. FLAIR (Study 201584).

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