

Administration and Characteristics of Cabotegravir Tablets

Summary

- The efficacy, safety, pharmacokinetics, stability, and physicochemical properties of cabotegravir tablets that have been split or crushed prior to administration have not been evaluated.
- To ensure administration of the entire dose of cabotegravir, the tablet should be swallowed whole to prevent loss of drug during preparation. Therefore, it is not recommended that cabotegravir tablets be split or crushed.
- For patients who cannot swallow, or have difficulty swallowing tablets whole, cabotegravir tablets may be split into halves immediately prior to administration. Additionally, cabotegravir tablets may be carefully crushed and added to a small amount of semi-solid food or liquid, all of which should be consumed immediately.
- Important safety information can be found in the <u>Prescribing Information link</u> and can also be accessed at <u>Our HIV Medicines</u>.

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ADMINISTRATION AND CHARACTERISTICS OF CABOTEGRAVIR TABLETS

Cabotegravir 30 mg tablets are intended to be used to assess the tolerability of cabotegravir prior to receiving the long-acting injectable form of the medicine or in place of the long-acting injectable medicine during a period of time (up to 2 months) when the injections cannot be administered on schedule.¹

The tablets are 8 mm x 14.3 mm and are oval and film-coated.^{1,2} The tablets are not scored.



SPLITTING AND CRUSHING

The efficacy, safety, pharmacokinetics, stability, and physicochemical properties of cabotegravir tablets that have been split or crushed prior to administration have not been evaluated.² To ensure administration of

the entire dose of a cabotegravir tablet, it should be swallowed whole to prevent loss of drug during preparation. Therefore, it is not recommended that cabotegravir tablets be split or crushed.

For patients who cannot swallow, or have difficulty swallowing tablets whole, cabotegravir tablets may be split into halves immediately prior to administration. Additionally, cabotegravir tablets may be carefully crushed and added to a small amount of semi-solid food or liquid, all of which should be consumed immediately. Crushing and mixing of cabotegravir tablets as described herein would not be expected to alter the intended clinical effect of cabotegravir tablets.

The conclusions for splitting or crushing cabotegravir tablets are based on the physicochemical and pharmacokinetic characteristics of the active ingredient and the overall stability profile of intact cabotegravir tablets.² It is assumed the patient or caregiver will perform the splitting or crushing process as practically close to dosing as possible with no loss of active ingredients and the patient ingests the mixture immediately.

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Some information contained in this response may not be included in the approved Prescribing information. This response is not intended to offer recommendations for administering this product in a manner inconsistent with its approved labeling. Please note that reports of adverse events in the published literature often lack causality assessments and may contain incomplete information; therefore, conclusions about causality generally cannot be drawn. In order 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. Please consult the Prescribing Information. This response was developed according to the principles of evidence-based medicine and, therefore, references may not be all-inclusive.



REFERENCES

- 1. ViiV Healthcare. Global Data Sheet for Cabotegravir (treatment). Version 08. October 24, 2022.
- 2. Data on File. 2019N425812.

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