Overview of *Triumeq PD* Tablets for Oral Suspension

Summary

- *Triumeq PD* (abacavir/dolutegravir/lamivudine, [ABC/DTG/3TC]) tablets for oral suspension are used for the treatment of HIV-1 infection in pediatric patients weighing at least 10 kg to < 25 kg.[1]
- *Triumeq PD* is not bioequivalent to or interchangeable with *Triumeq* film-coated tablets.[1] The relative bioavailability of dolutegravir in *Triumeq PD* is approximately 1.7-fold higher than *Triumeq* film-coated tablets.
- The dose of *Triumeq PD* is dependent on weight.[1] *Triumeq PD* is not recommended in patients weighing 25 kg or more and should not be used in adults.
- *Triumeq PD* must be dispersed in clean drinking water.[1] Do not use any other drink or food to prepare the dose. When the tablets are gently swirled in water, the medicine will become cloudy. The dose should be administered within 30 minutes. If it has been more than 30 minutes, a new dose should be prepared. *Triumeq PD* may be taken with or without food.
- Important safety information and boxed warning(s) can be found in the Prescribing Information link and can also be accessed at Our HIV Medicines.

To access additional scientific information related to ViiV Healthcare medicines, visit the ViiV US Medical Portal at viivhcmedinfo.com.

INDICATION

Triumeq PD tablets for oral suspension are indicated for the treatment of HIV-1 in patients weighing at least 10 kg to < 25 kg.[1]

Triumeq PD is not recommended in patients with resistance-associated integrase substitutions or clinically suspected integrase strand transfer inhibitor resistance because the dose of dolutegravir in *Triumeq PD* is insufficient in these subpopulations.[1]

DOSE

Please see Table 1 for *Triumeq PD* dosing recommendations in children weighing at least 10 kg.[1] Note that Triumeq is available in two dosage forms. Only the *Triumeq PD* tablets for oral suspension should be used in patients weighing 10 kg to < 25 kg.; *Triumeq* film-coated tablets should not be used in pediatric patients weighing 10 kg to < 25 kg.

Table 1. Dosing Recommendations for *Triumeq* and *Triumeq PD* Tablets for Oral Suspension in Pediatric Patients[1]

Body Weight	*Triumeq* Tablets[a]	*Triumeq PD*[b] Number of Tablets	Total Daily Dose
10 kg to < 14 kg	Not recommended	4 tablets once daily	240 mg abacavir, 20 mg dolutegravir, and 120 mg lamivudine once daily
14 kg to < 20 kg	Not recommended	5 tablets once daily	300 mg abacavir, 25 mg dolutegravir, and 150 mg lamivudine once daily
20 kg to < 25 kg	Not recommended	6 tablets once daily	360 mg abacavir, 30 mg dolutegravir, and 180 mg lamivudine once daily
≥ 25 kg	1 tablet once daily	Not recommended	600 mg abacavir, 50 mg dolutegravir, and 300 mg lamivudine

[a] *Triumeq* is a fixed-dose combination product containing 600 mg of abacavir, 50 mg of dolutegravir, and 300 mg of lamivudine; [b] *Triumeq PD* is a fixed-dose combination product containing 60 mg of abacavir, 5 mg of dolutegravir, and 30 mg of lamivudine

PHARMACOKINETICS AND INTERCHANGEABILITY

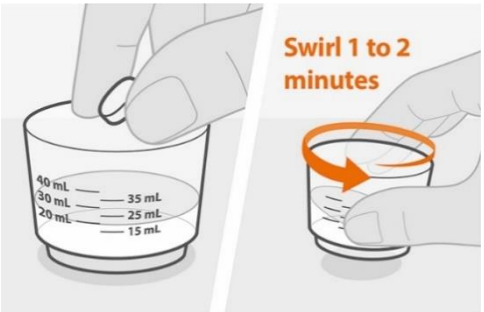
Triumeq film-coated tablets and *Triumeq PD* are not bioequivalent and not interchangeable.[1] The relative dolutegravir bioavailability of *Triumeq PD* is approximately 1.7-fold higher than *Triumeq* film-coated tablets.

The pharmacokinetics (PK) for the individual components of *Triumeq* and *Triumeq PD* have been evaluated in pediatric participants.[2] The PK of dolutegravir were evaluated in the IMPAACT P1093 trial and in 2 weight-band-based PK substudies from the ODYSSEY trial. Mean dolutegravir $AUC_{0\text{-}24h}$ and C_{24h} in HIV-1-infected pediatric participants weighing at least 10 kg were comparable to those in adults after 50 mg once daily or 50 mg twice daily. Mean C_{max} was higher in pediatrics, but the increase is not considered clinically significant as the safety profiles were similar in pediatric and adult participants. In pediatric patients weighing 10 to < 25 kg, predicted exposures ($AUC_{0\text{-}24h}$) of ABC and 3TC at the recommended doses for *Triumeq PD* are within the predicted exposure range of the individual components based on population PK modeling and simulation.[2]

ADMINISTRATION

Disperse the prescribed number of *Triumeq PD* tablets in 20 mL of clean drinking water in the supplied cup.[1] The cup should be gently swirled for 1-2 minutes to disperse the tablets in the water (see Figure 1). The medicine will become cloudy. If lumps appear, continue to swirl the cup gently until all the medicine is dissolved. Make sure the child is upright and give all the prepared medicine. Add another 15 mL or less of water to the cup, swirl, and give it all to the child. Repeat if any remains to ensure that the child gets the full dose.

Figure 1. Preparation of ABC/DTG/3TC[1]



The efficacy, safety, and stability of *Triumeq PD* following administration of *Triumeq PD* that have been dispersed in liquids other than water have not been evaluated.[3] Triumeq PD tablets for oral suspension must be dispersed in drinking water only. Do not use any other drink or food to prepare the dose.

Triumeq PD tablets for oral suspension should be fully dispersed in water before swallowing, and the dose should be administered orally within 30 minutes. If it has been more than 30 minutes, wash away all the dose in the cup using water and prepare a new dose of medicine. *Triumeq PD* should not be chewed, cut, or crushed.

Triumeq PD may be taken with or without food.

HOW SUPPLIED

Each tablet contains 60 mg of abacavir (as abacavir sulfate), 5 mg of dolutegravir (as dolutegravir sodium), and 30 mg lamivudine.[1] Tablets are yellow, capsule-shaped, strawberry cream flavored, film-coated, biconvex tablets debossed with "SV WTU" on one side. Bottles are supplied with 90 tablets with child-resistant closure containing a desiccant. Each bottle is packaged with one 40-mL dosing cup.

STORAGE

Store *Triumeq PD* tablets at 20°C to 25°C (68°F to 86°F); excursions permitted between 15°C and 30°C (59°F to 86°F).[1] Store and dispense in the original bottle, protect from moisture, and keep the bottle tightly closed. Do not remove the desiccant.

This information is scientific and non-promotional in nature and is not intended for further distribution.

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 Local Label.
2. ViiV Healthcare. Global Data Sheet for abacavir/dolutegravir/lamivudine, Version 0019, August 17, 2023.
3. Data on File. 2022N502569_00.