Prezcobix® (darunavir/cobicistat) – Expanded indication

- On March 21, 2025, the FDA approved Janssen's Prezcobix (darunavir/cobicistat), in combination with other antiretroviral agents, for the **treatment of HIV-1 in treatment-naïve and treatment-experienced adults and pediatric patients weighing at least 25 kg with no darunavir resistance-associated substitutions (V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V)**.
    - Prezcobix was previously approved for this indication in pediatric patients weighing at least 40 kg.
- In addition to the expanded indication, the FDA approved a new fixed dose tablet containing 675 mg of darunavir and 150 mg of cobicistat.
- The recommended dose of Prezcobix for the treatment of pediatric patients weighing at least 25 kg to less than 40 kg is **one 675 mg darunavir/150 mg cobicistat tablet once daily**.
    - Refer to the Prezcobix drug label for dosing for adults and pediatric patients weighing at least 40 kg.
- Janssen's launch plans for the new strength of Prezcobix are pending.

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