

Mydayis® (mixed-salts of a single-entity amphetamine product) – First-time generic

- On October 10, 2023, <u>Teva launched</u> an <u>AB-rated</u> generic version of Takeda's <u>Mydayis (mixed-salts of a single-entity amphetamine product) extended-release capsules.</u>
 - Mydayis is a schedule II controlled substance.
 - SpecGX and Sun received FDA approval of AB-rated generic versions of Mydayis on August 31, 2023 and September 27, 2023, respectively. Launch plans are pending.
- Mydayis is approved for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 13 years and older.
- Other combination mixed salts amphetamine products are available: brand and generic <u>Adderall®</u> tablets and brand and generic <u>Adderall XR®</u> capsules.
 - Adderall and Adderall XR are both indicated for ADHD; Adderall is also approved for narcolepsy.
- Mydayis carries a boxed warning for abuse and dependence.



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