

Hetlioz® (tasimelteon) - First-time generic update

- On December 29, 2022, <u>Teva launched an AB-rated generic version of Vanda</u>—s <u>Hetlioz</u> (tasimelteon) capsules.
 - Apotex received FDA-approval of an <u>AB-rated generic</u> version of Hetlioz on December 20, 2022. Launch plans are pending.
- Hetlioz capsules are approved for the treatment of non-24-hour sleep-wake disorder in adults, and for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome in patients 16 years of age and older.
- Teva received FDA approval of <u>tasimelteon</u> for the treatment of non-24-hour sleep-wake disorder in adults.



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