COMMUNICATION

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PLEASE REVIEW

# Drug Information

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information requested.

## Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252-Clinical Department.

Access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

## FDA Approves First Generics of ADHD and BED Treatment

The Food and Drug Administration (FDA) has approved several first generics of Vyvanse™ (lisdexamfetamine dimesylate) capsules and chewable tablets for attention-deficit/hyperactivity disorder (ADHD) in patients six years and older and moderate to severe binge-eating disorder (BED) in adults.

### Background Information

ADHD is one of the most common neurodevelopmental disorders of childhood. It is often diagnosed in childhood and often lasts into adulthood. It affects around 10% of the pediatric population and 4.4% of the adult population.

BED is a severe, life-threatening, and treatable eating disorder. The condition currently affects 2.8 million adults in the U.S. Vyvanse™, and now its generic, is the only drug approved by the FDA for binge-eating disorder. It was approved by the FDA in 2007 to treat patients with ADHD and in 2015 to treat patients with binge-eating disorder.

### Shortage and Generics Availability:

Vyvanse™ has being experiencing shortages of some of its products, including 60mg capsules and 70mg capsules in 100-count bottles, because of manufacturing delay and increasing demand.

The FDA has given the approval to 15 different manufacturers.

Generic capsule manufacturers: Actavis Elizabeth LLC; Alkem Laboratories Limited; Amneal Pharmaceuticals LLC (excl. 10 mg); Apotex Corp.; Ascent Pharmaceuticals, Inc.; Hikma Pharmaceuticals USA Inc. (excl. 10 mg); Lannett Company, Inc.; Mylan Pharmaceuticals Inc.; Norwich Pharmaceuticals, Inc.; Prinston Pharmaceutical Inc.; Rhodes Pharmaceuticals L.P.; SpecGx LLC; Sun Pharmaceutical Industries, Inc.

Generic chewable tablet manufacturers: Ascent Pharmaceuticals, Inc.; Sun Pharmaceutical Industries, Inc.; Teva Pharmaceuticals USA, Inc.

Additional information can be found at:

- FDA Approves Multiple Generics of ADHD and BED Treatment

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REFERENCES:

1. Center for Drug Evaluation and Research. (2023). *FDA approves multiple generics of ADHD and bed treatment*. U.S. Food and Drug Administration. https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-multiple-generics-adhd-and-bed-treatment
2. *New generic drug approvals for 2023*. Drugs.com. (2023). https://www.drugs.com/generic-approvals.html
3. Centers for Disease Control and Prevention. (2022, August 9). What is ADHD?. Centers for Disease Control and Prevention. https://www.cdc.gov/ncbddd/adhd/facts.html
4. *Binge eating disorder*. National Eating Disorders Association. (2018, February 22). https://www.nationaleatingdisorders.org/learn/by-eating-disorder/bed

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