

## Synjardy® (empagliflozin/metformin) – Expanded Indication

- On July 19, 2016, <u>Boehringer Ingelheim announced</u> the FDA approval of <u>Synjardy</u>
  (<u>empagliflozin/metformin</u>) tablets, as an adjunct to diet and exercise to improve glycemic control in adults
  with type 2 diabetes mellitus (T2DM) when treatment with both empagliflozin and metformin is
  appropriate.
  - This approval extends Synjardy use to treatment-naïve adults with T2DM.
  - Previously, Synjardy was approved in adults with T2DM who were not adequately controlled on a regimen containing empagliflozin or metformin, or in patients already being treated with both empagliflozin and metformin
- The expanded indication for Synjardy was approved based on an active-controlled study that evaluated empagliflozin in combination with metformin as initial therapy vs. the individual components.
  - At 24 weeks, the combination of empagliflozin (10 mg or 25 mg) with metformin (1,000 mg or 2,000 mg) resulted in significant reductions in average blood glucose levels compared with the corresponding dose of either component alone.
- Similar to other metformin-containing products, Synjardy carries a boxed warning regarding the risk of lactic acidosis.
- The recommended dose of Synjardy should be individualized based on the patient's current regimen. The maximum recommended oral dose is 12.5 mg empagliflozin/1,000 mg metformin twice daily.
  - Synjardy is contraindicated in patients with estimated glomerular filtration rate below 45 mL/min/1.73m<sup>2</sup>.



## optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

Rx News® is published by the OptumRx Clinical Services Department.

©2016 Optum, Inc. All rights reserved.