COM-2023-036

28 June

PLEASE Drug Information REVIEW PharmPix Clinical Department

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.

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

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

SGLT2 Inhibitors Indicated to Treat Pediatric Type 2 Diabetes

The U.S. Food and Drug Administration (FDA) has approved Boehringer Ingelheim and Lilly's empagliflozin (Jardiance™) plus empagliflozin and metformin (Synjardy™) as an addition to diet and exercise to improve blood sugar control in pediatric patients aged 10 years and older with type 2 diabetes (T2D).

What does the American Diabetes Association (ADA) Recommends?

Treatment of youth-onset type 2 diabetes should include lifestyle management, diabetes self-management education and support, and pharmacologic treatment. Current pharmacologic treatment options are limited to three approved drug classes: insulin, biguanides (metformin), and glucagon-like peptide 1 receptor agonists. Out of the three approved drug classes, metformin is the only oral option. Initial therapy depends on A1C and presence of complications such as acidosis, ketosis. diabetic ketoacidosis, hyperosmolar hyperglycemic state. For new-onset diabetes with an A1C less than 8.5% and no acidosis or ketosis, metformin is first-line treatment option.

SGLT2 Inhibitors for Pediatric Patients

With this approval by the FDA, two oral sodium-glucose cotransporter-2 (SGLT2) inhibitors are now indicated in the pediatric population (Jardiance™ and Synjardy™). This offers a new class of oral medications that treat pediatric T2D. Prior to this clearance, the only other therapy FDA-approved for children in type 2 diabetes was metformin. It was approved back in 2000.

The FDA approval of Jardiance™ and Synjardy™ in the pediatric population is based on the results from the DINAMO study that showed empagliflozin was associated with a statistically significant reduction of change from baseline in A1C levels at 26 weeks compared with the placebo. The safety profile was consistent with the previously known safety profile of empagliflozin. Common adverse effects in children administered empagliflozin were generally similar to those observed in adults, other than a greater risk of hypoglycemia among pediatric patients 10 years and older.



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