

New Oral Option for Type 2 Diabetes Approved by FDA

In January 2014, the FDA approved Farxiga (dapagliflozin), an orally-active sodium glucose cotransporter type 2 (SGLT-2) inhibitor. Farxiga, created by Bristol-Myers Squibb and AstraZeneca Pharmaceuticals, is only the second medication in the United States to utilize this novel mechanism in order to combat elevated blood glucose levels. Farxiga, along with its competitor Invokana (canagliflozin; Janssen Pharmaceuticals), works by blocking reabsorption of glucose in the kidney at the aforementioned SGLT-2 transporters. This blockade increases the amount of glucose excreted through the urine, and, when combined with diet and exercise, helps to improve glycemic control in patients with type 2 diabetes.

Farxiga is to be initiated at 5mg once daily in the morning taken with or without food. A titration up to 10mg once daily can be performed in patients who require tighter glycemic control. No adjustments are required in geriatric patients or those with hepatic impairment. Adverse effects at these recommended doses include increases in female genital mycotic infections, nasopharyngitis, and urinary tract infections. Farxiga is contraindicated in moderate kidney impairment with eGFR $<60\text{mL/min/1.73m}^2$, should be used with caution in those with pre-existing or history of bladder cancer, and is not intended to treat patients with type 1 diabetes or those in diabetic ketoacidosis. As increased urination can lead to dehydration and hypotension, caution should be exercised when combining Farxiga with diuretic therapy.

The studies leading to Farxiga's approval demonstrated a drop in A1c of 0.8% (5mg) and 0.9% (10mg) along with a drop in fasting blood glucose of 24.1mg/dL (5mg) and 28.8mg/dL (10mg). Farxiga was also studied as add-on therapy with glipizide, metformin, pioglitazone, sitagliptin, and insulin. In these studies, the addition of Farxiga to any of the previous agents appeared to provide an increase in efficacy when compared to the use of either agent alone. In addition to this pre-existing research, the FDA is also requiring further post-market investigation into cardiovascular outcomes and bladder cancer risk with use of Farxiga along with safety/efficacy in pediatric populations.

Farxiga is available in packages of 30 tablets of 5mg (NDC 00003-1427-11) or 10mg (NDC 00003-1428-11) for \$347.04 AWP each.

References:

- 1) FDA approves Farxiga to treat type 2 diabetes. FDA. Available at: <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm380829.htm>
- 2) Dapagliflozin Propanediol. In: Redbook Online System [Internet Database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed: January 22, 2014.
- 3) Dapagliflozin. In: DRUGDEX® System [Internet Database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed: January 22, 2014.
- 4) Farxiga Package Insert. Bristol-Myers Squibb . http://packageinserts.bms.com/pi/pi_farxiga.pdf

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