# DRUG DISCOVERY

FDA Approved Drugs - January 2014

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#### **Publication History**

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#### 1. FARXIGA (DAPAGLIFLOZIN)

#### 1.1. Company

Bristol-Myers Squibb; Approved by January 2014

#### 1.2. Treatment Area

Type II diabetes

### 1.3. General Information

Farxiga (dapagliflozin) is an orally active sodium glucose cotransporter type 2 (SGLT-2) inhibitor. Inhibiting SGLT2 activity modulates reabsorption of glucose in the kidney, resulting in excretion of glucose in the urine. It is specifically indicated as an adjunct to diet and exercise to improve glycemic control in adults with type II diabetes mellitus. It is supplied as a tablet for oral administration. The recommended starting dose is 5 mg once daily, taken in the morning, with or without food. The dose can be increased to 10 mg once daily in patients tolerating Farxiga who require additional glycemic control. Renal function should be assessed before initiating Farxiga. Do not initiate Farxiga if eGFR is below 60 mL/min/1.73 m2. Farxiga should be discontinued if eGFR falls persistently below 60 mL/min/1.73 m2.

### 1.4. Mechanism of Action

Farxiga (dapagliflozin) is an inhibitor of Sodium-glucose cotransporter 2 (SGLT2). SGLT2 is expressed in the proximal renal tubules and is responsible for the majority of the reabsorption of filtered glucose from the tubular lumen. By inhibiting SGLT2, dapagliflozin reduces reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion.

#### 1.5. Side Effects

Adverse events associated with the use of Farxiga includes: female genital mycotic infections, nasopharyngitis, urinary tract infections

#### 2. HETLIOZ (TASIMELTEON)

#### 2.1. Company

Vanda Pharmaceuticals; Approved by January 2014



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#### 2.2. Treatment Area

Non-24-hour sleep-wake disorder in the totally blind

#### 2.3. General Information

Hetlioz is specifically indicated for the treatment of non-24-hour sleep-wake disorder in the totally blind. It is supplied as a capsule for oral administration. The recommended dosage of Hetlioz is 20 mg per day taken before bedtime, at the same time every night. Because of individual differences in circadian rhythms, drug effect may not occur for weeks or months.

#### 2.4. Mechanism of Action

Hetlioz (tasimelteon) is an agonist at melatonin MT1 and MT2 receptors. These receptors are thought to be involved in the control of circadian rhythms. The precise mechanism by which tasimelteon exerts its therapeutic effect in patients with Non 24 is not known.

#### 2.5. Side Effects

Adverse events associated with the use of Hetlioz includes: headache, increased alanine aminotransferase, nightmares or unusual dreams, upper respiratory or urinary tract infection