Duzallo® (lesinurad/allopurinol) – New drug approval

- On August 21, 2017, Ironwood Pharmaceuticals announced the FDA approval of Duzallo (lesinurad/allopurinol), for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a medically appropriate daily dose of allopurinol alone.
    - Duzallo is not recommended for the treatment of asymptomatic hyperuricemia.
- Gout is the most common inflammatory arthritis in adults. It is a highly symptomatic and painful disease caused by high serum uric acid levels in the blood (hyperuricemia).
    - An estimated 2 million Americans currently treated with a xanthine oxidase inhibitor suffer from uncontrolled gout.
- Duzallo contains a uric acid transporter 1 inhibitor (Zurampic® [lesinurad]) and a xanthine oxidase inhibitor (allopurinol).
- There have been no phase 3 clinical trials with Duzallo. Bioequivalence of Duzallo to co-administered lesinurad and allopurinol was demonstrated, and efficacy of the combination of lesinurad and allopurinol has been demonstrated in two phase 3 studies.
- Duzallo carries a boxed warning regarding the risk of acute renal failure.
- Duzallo is contraindicated in the following conditions: severe renal impairment, end-stage renal disease, kidney transplant recipients, or patients on dialysis; tumor lysis syndrome or Lesch-Nyhan syndrome; and known hypersensitivity to allopurinol, including previous occurrence of skin rash.
- Warnings and precautions of Duzallo include renal events, skin rash and hypersensitivity, hepatotoxicity, cardiovascular events, bone marrow depression, increase in prothrombin time, and drowsiness.
- The most common adverse reactions (≥ 2% and more frequently than on oxidase inhibitor alone) with lesinurad in combination with a xanthine oxidase inhibitor use were headache, influenza, increased blood creatinine, and gastroesophageal reflux.
- The most frequently reported adverse reaction for allopurinol is skin rash.
- The recommended dose of Duzallo is 1 tablet orally once daily in the morning. Patients should use one tablet of Duzallo in place of an equivalent portion of the total daily allopurinol dose. The total daily dose of allopurinol should be maintained at the time of initiating Duzallo.
    - One tablet of Duzallo contains the maximum daily lesinurad dose of 200 mg.
    - The use of Duzallo is not recommended for patients taking daily doses of allopurinol less than 300 mg (or less than 200 mg in patients with estimated creatinine clearance less than 60 mL/min).
    - For patients currently on Zurampic in combination with allopurinol, Duzallo may be initiated by using one tablet of Duzallo in place of Zurampic and an equivalent portion of the daily allopurinol dose.
    - For further details refer to the Duzallo drug label.

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- Ironwood plans to launch Duzallo early in the 4th quarter of 2017. Duzallo will be available as tablets containing 200 mg lesinurad/200 mg allopurinol and 200 mg lesinurad/300 mg allopurinol.