Coxanto (oxaprozin) – New drug approval

- On October 20, 2023, the FDA approved Solubiomix's Coxanto (oxaprozin), for relief of the signs and symptoms of osteoarthritis (OA), rheumatoid arthritis (RA), and juvenile rheumatoid arthritis (JRA).
- Coxanto is a non-steroidal anti-inflammatory drug (NSAID). The active ingredient, oxaprozin, is currently available generically for the same indications as Coxanto.
- The approval of Coxanto was based on clinical studies using other formulations of oxaprozin.
- Coxanto carries a boxed warning for risk of serious cardiovascular and gastrointestinal events.
- Coxanto is contraindicated in the following patients:
    - Known hypersensitivity to oxaprozin or any components of the drug product
    - History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs
    - In the setting of coronary artery bypass graft (CABG).
- Refer to the Coxanto drug label for a complete listing of its warnings and precautions.
- The most common adverse reactions (> 3%) with Coxanto use were constipation, diarrhea, dyspepsia, nausea, rash.
- The recommended dose of Coxanto is:
    - OA and RA: 1,200 mg given orally once a day
    - JRA (in patients 6 to 16 years of age): 600 mg to 1,200 mg given orally once a day (dose depends on body weight).
- Different dose strengths and formulations (eg, capsules, tablets) of oral oxaprozin are not interchangeable. This difference should be taken into consideration when changing strengths or formulations.
- Solubiomix's launch plans for Coxanto are pending. Coxanto will be available as a 300 mg capsule.

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