



### Vivlodex™ (meloxicam) – New Formulation Approval

- On October 23, 2015, [Iroko announced](#) the approval of [Vivlodex \(meloxicam\)](#), for the management of osteoarthritis (OA) pain.
- OA affects about 27 million people in the U.S. People with OA experience pain and stiffness in and around one or more joints.
- Vivlodex is a nonsteroidal anti-inflammatory drug (NSAID) that has analgesic, anti-inflammatory, and fever-reducing properties. Vivlodex is a low dose [meloxicam](#) developed with SoluMatrix® technology. This technology uses very small particle size meloxicam.
- The efficacy and safety of Vivlodex were based on a double-blind, placebo-controlled study of 402 patients with OA of the hip or knee.
  - Vivlodex 5 mg and 10 mg once daily significantly reduced OA pain compared with placebo at 12 weeks (5 mg,  $p = 0.0005$ ; 10 mg,  $p = 0.0059$ ).
- Vivlodex is contraindicated in patients with known hypersensitivity to meloxicam or any components of the drug product, history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs, and in the setting of coronary artery bypass graft (CABG) surgery.
- Similar to other NSAIDs, Vivlodex carries a boxed warning for risk of serious cardiovascular and gastrointestinal events.
- Other warnings and precautions of Vivlodex include hepatotoxicity, hypertension, heart failure and edema, renal toxicity and hyperkalemia, anaphylactic reactions, exacerbation of asthma related to aspirin sensitivity, serious skin reactions, premature closure of fetal ductus arteriosus, hematologic toxicity, masking of inflammation and fever, and laboratory monitoring.
- The most common adverse events ( $\geq 2\%$ ) with Vivlodex use were diarrhea, nausea, and abdominal discomfort.
- The recommended dose of Vivlodex is 5 mg orally once daily. In patients who require additional analgesia, the dose may be increased to 10 mg per day.
  - Vivlodex capsules are not interchangeable with other formulations of oral meloxicam even if the milligram strength is the same.
  - Vivlodex should be used at the lowest effective dosage for the shortest duration consistent with individual patient treatment goals.
- The launch date for Vivlodex is pending. Vivlodex will be available as 5 mg and 10 mg capsules.



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