

VIVLODEX™ (meloxicam) Capsules

Fact Sheet



VIVLODEX™ is the third low dose nonsteroidal anti-inflammatory drug (NSAID) approved by the U.S. Food and Drug Administration (FDA) developed using SoluMatrix Fine Particle Technology™. VIVLODEX was developed to align with recommendations from FDA that NSAIDs be used at the lowest effective dose for the shortest possible duration.¹ VIVLODEX is indicated for the management of osteoarthritis pain.²

About VIVLODEX

VIVLODEX was created using SoluMatrix Fine Particle Technology™ and contains meloxicam as submicron particles that are approximately 10 times smaller than their original size. The reduction in particle size provides an increased surface area, leading to faster dissolution.³

VIVLODEX Pivotal Phase 3 Data

FDA approval of VIVLODEX was supported by data from a Phase 3, multi-center, double-blind and placebo-controlled study in 402 patients, aged 40 and older, with pain due to osteoarthritis of the knee or hip, who were randomized to receive treatment with once-daily VIVLODEX 5 mg, VIVLODEX 10 mg, or placebo over a period of 12 weeks.⁴ The VIVLODEX dose strengths studied achieved efficacy at 33 percent lower doses than currently available meloxicam products.³ The primary efficacy endpoint was the mean change from baseline in the WOMAC pain subscale score at week 12, analyzed by mixed-model repeated measures (MMRM) analysis. Secondary efficacy endpoints included the Patient Global Impression of Change (PGIC), a patient reported outcome measure, as well as the amount of rescue medication (acetaminophen) used by each patient.⁴

At week 12, patients treated with VIVLODEX 5 mg ($P = 0.0005$) and 10 mg ($P = 0.0059$) achieved significantly greater pain relief as measured by the WOMAC pain subscale score compared with placebo. Based on PGIC, a greater number of patients reported their condition as “very much improved” or “much improved” following treatment with VIVLODEX 5 mg (50%) or 10 mg (52%) compared with patients in the placebo control group (40%). Patients in the VIVLODEX 5 mg ($P = 0.006$) and 10 mg ($P = 0.0013$) treatment groups used significantly less rescue medication compared with patients in the placebo group.⁴

Dosing

For management of OA pain the starting dose is 5 mg orally once daily. Dose may be increased to 10 mg in patients who require additional analgesia. VIVLODEX should be used at the lowest effective dosage for the shortest duration consistent with individual patient treatment goals and is not interchangeable with other formulations of oral meloxicam even if the total milligram strength is the same.²

Safety

Most common adverse reactions (incidence $\geq 2\%$ in VIVLODEX 5 mg or 10 mg group) include: diarrhea, nausea, and abdominal discomfort.²

Indication

VIVLODEX is indicated for the management of osteoarthritis pain.

Important Safety Information

Cardiovascular Thrombotic Events

Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular (CV) thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.

VIVLODEX is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Bleeding, Ulceration, and Perforation

NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

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VIVLODEX is contraindicated in patients with: a known hypersensitivity to meloxicam or its inactive ingredients; a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.

VIVLODEX should be used at the lowest effective dosage for the shortest duration consistent with individual patient treatment goals.

Elevation of one or more liver tests may occur during therapy with VIVLODEX. Rare, sometimes fatal, cases of severe hepatic injury have been reported. VIVLODEX should be discontinued immediately if clinical signs and symptoms of liver disease develop.

NSAIDs, including VIVLODEX, can lead to the new onset or worsening of existing hypertension, which may contribute to the increased incidence of CV events. Blood pressure should be monitored during treatment with VIVLODEX. NSAIDs may diminish the antihypertensive activity of loop and thiazide diuretics, ACE inhibitors, angiotensin receptor blockers, or beta-blockers.

NSAID use has been associated with an increase in the risk of MI, hospitalizations due to heart failure, and death. Also, fluid retention and edema have been observed in patients taking NSAIDs. Avoid the use of VIVLODEX in patients with severe heart failure.

Long-term administration of NSAIDs can result in renal papillary necrosis and other renal injury. VIVLODEX should be used with caution in patients at greatest risk of this reaction, including the elderly, those with impaired renal function, heart failure, liver dysfunction, dehydration, hypovolemia, and those taking diuretics and ACE inhibitors. Avoid the use of VIVLODEX in patients with advanced renal disease. Increases in serum potassium levels, including hyperkalemia, have been reported with NSAID use.

Anaphylactic reactions may occur in patients with the aspirin triad or in patients without prior exposure to VIVLODEX and should be discontinued immediately if an anaphylactic reaction occurs.

NSAIDs can cause serious skin adverse events such as exfoliative dermatitis, Stevens - Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. VIVLODEX should be discontinued if rash or other signs of local skin reaction occur.

Starting at 30 weeks of gestation, VIVLODEX and other NSAIDs should be avoided by pregnant women as premature closure of the ductus arteriosus in the fetus may occur.

Concomitant administration of anticoagulants, antiplatelet agents (e.g., aspirin), SSRIs, SNRIs, salicylates, or other NSAIDs with VIVLODEX may increase the risk of bleeding.

The anti-inflammatory and anti-pyretic activity of VIVLODEX may mask the signs of infection.

Since serious GI, hepatic, and renal events have been reported with NSAID use, consider monitoring CBC and chemistry profile in patients on long-term NSAID therapy.

Most common adverse reactions in clinical trials (incidence ≥2%) include: diarrhea, nausea, and abdominal discomfort.

VIVLODEX capsules do not result in an equivalent systemic exposure to other formulations of oral meloxicam. Therefore, do not substitute similar dosing strengths of other meloxicam products for VIVLODEX.

Please see full Prescribing Information for additional important safety and dosing information.

¹ U.S. Food and Drug Administration. 2005 Public Health Advisory – FDA Announces Important Changes and Additional Warnings for COX-2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

² VIVLODEX full Prescribing Information. 2015. Iroko Pharmaceuticals, LLC.

³ Iroko Pharmaceuticals, LLC. Data on file.

⁴ Altman, R., et al. Lower-Dose SoluMatrix® Meloxicam: Efficacy and Safety in a Phase 3 Study in Adults with Osteoarthritis Pain. Final Poster Presentation for 2014 European League Against Rheumatism (EULAR) Annual European Congress of Rheumatology.