

## FIRST TIME GENERIC APPROVAL

<b>Brand Name</b>	Vivlodex™
<b>Generic Name</b>	meloxicam
<b>Drug Manufacturer</b>	Lupin Limited

### New Drug Approval

#### TYPE OF CLINICAL UPDATE

First time generic

#### FDA APPROVAL DATE

June 01, 2020

#### LAUNCH DATE

N/A

#### REVIEW DESIGNATION

Standard

#### TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 209487

#### DISPENSING RESTRICTIONS

N/A

### Overview

#### INDICATION FOR USE

Meloxicam capsule is a non-steroidal anti-inflammatory drug indicated for management of osteoarthritis (OA) pain.

#### MECHANISMS OF ACTION

Meloxicam has analgesic, anti-inflammatory, and antipyretic properties. The mechanism of action of meloxicam, like that of other NSAIDs, is not completely understood but involves inhibition of cyclooxygenase (COX-1 and COX-2).

Meloxicam is a potent inhibitor of prostaglandin synthesis in vitro. Meloxicam concentrations reached during therapy have produced in vivo effects. Prostaglandins sensitize afferent nerves and potentiate the action of bradykinin in inducing pain in animal models. Prostaglandins are mediators of inflammation. Because meloxicam is an inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissues.

#### DOSE FORM AND STRENGTH

Capsules: 5 mg, 10 mg

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### DOSE & ADMINISTRATION

- Start with 5 mg orally once daily. May increase dose to 10 mg in patients who require additional analgesia. Use the lowest effective dose for shortest duration consistent with individual patient treatment goals.
- Meloxicam capsules are not interchangeable with other formulations of oral meloxicam even if the milligram strength is the same.

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