

Qamzova[™] (meloxicam) - New drug approval

- On April 22, 2025, the FDA approved Nanjing Delova Biotech's Qamzova (meloxicam), for use in adults for the management of moderate-to-severe pain, alone or in combination with non-nonsteroidal anti-inflammatory drug (NSAID) analgesics.
- Meloxicam is currently available generically as an oral tablet and suspension.
- Qamzova carries a boxed warning for risk of serious cardiovascular and gastrointestinal events.
- Qamzova is contraindicated in patients:
 - Known hypersensitivity (eg, anaphylactic reactions and serious skin reactions) to meloxicam 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 surgery
 - Moderate to severe renal insufficiency patients who are at risk for renal failure due to volume depletion.
- Additional warnings and precautions for Qamzova include hepatotoxicity; hypertension; heart failure and edema; renal toxicity and hyperkalemia; anaphylactic reactions; exacerbation of asthma related to aspirin sensitivity; serious skin reactions; drug rash with eosinophilia and systemic symptoms; fetal toxicity; hematologic toxicity; masking of inflammation and fever; and laboratory monitoring.
- The most common adverse reactions (≥ 2% and greater than placebo) with Qamzova use are constipation, increased gamma-glutamyl transferase, and anemia.
- The recommended dose of Qamzova is 30 mg once daily, administered by intravenous bolus injection over 15 seconds.
 - Some patients may not experience adequate analgesia for the entire 24-hour dosing interval and may require administration of a short-acting, non-NSAID, immediate-release analgesic.
- Nanjing Delova Biotech's launch plans for Qamzova are pending. Qamzova will be available as a 30 mg/mL single-dose vial.



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