Qmiiz ODT™ (meloxicam) – New drug approval

- On October 19, 2018, the FDA announced the approval of TerSera Therapeutics' Qmiiz ODT (meloxicam), for the relief of the signs and symptoms of osteoarthritis (OA) in adults; rheumatoid arthritis (RA) in adults; and pauciarticular and polyarticular course juvenile rheumatoid arthritis (JRA) in pediatric patients who weigh greater than or equal to 60 kg.

- Meloxicam is also available generically as tablets and brand name capsules (Vivlodex™).

    — Meloxicam tablets are approved for the same indications as Qmiiz ODT.
    — Vivlodex is only indicated for the management of OA pain.

- The efficacy and safety of Qmiiz ODT is based on prior clinical studies evaluating meloxicam is the treatment of OA, RA, and pauciarticular and polyarticular course JRA.

- Qmiiz ODT carries a boxed warning for risk of serious cardiovascular and gastrointestinal events.

- Qmiiz ODT is contraindicated in patients with a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other nonsteroidal anti-inflammatory drugs; history of phenylketonuria; in the setting of coronary artery bypass grafting surgery; and with known hypersensitivity to meloxicam or any components of the drug product.

- Warnings and precautions of Qmiiz ODT include cardiovascular thrombotic events; gastrointestinal bleeding, ulceration, and perforation; 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 reactions (≥ 5%) with Qmiiz ODT use in adults were diarrhea, upper respiratory tract infections, dyspepsia, and influenza-like symptoms. Adverse events observed in pediatric studies were similar in nature to the adult clinical trial experience.

- The recommended starting and maintenance dose of Qmiiz ODT for OA and RA is 7.5 mg once daily. Some patients may receive additional benefit by increasing the dose to 15 mg once daily.

- The recommended dose of Qmiiz ODT for JRA is 7.5 mg once daily in children who weigh ≥ 60 kg. There was no additional benefit demonstrated by increasing the dose above 7.5 mg in clinical trials.

- Carefully consider the potential benefits and risks of Qmiiz ODT and other treatment options before deciding to use Qmiiz ODT. Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals.

    — The tablet will disintegrate quickly in saliva and can be easily swallowed with or without drinking liquid.

- TerSera Therapeutics launch plans for Qmiiz ODT are pending. Qmiiz ODT will be available as 7.5 mg or 15 mg orally disintegrating tablets.

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