CLINICAL UPDATE

Brand Name	Loreev XR®
Generic Name	lorazepam
Drug Manufacturer	Almatica Pharma LLC

Clinical Update

TYPE OF CLINICAL UPDATE

New Dosage Form

FDA APPROVAL DATE

August 27, 2021

LAUNCH DATE

August 31, 2021

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Type 3 - New Dosage Form, New Drug Application (NDA): 214826

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION(S) FOR USE

Loreev XR® is a benzodiazepine indicated for the treatment of anxiety disorders in adults who are receiving stable, evenly divided, three times daily dosing with lorazepam tablets.

MECHANISMS OF ACTION

Lorazepam exerts its effect for the treatment of anxiety disorders through binding to the benzodiazepine site of the gamma-aminobutyric acid-A (GABAA) receptors in the brain and enhances GABA-mediated synaptic inhibition.

DOSAGE FORM(S) AND STRENGTH(S)

Extended-release capsules: 1 mg, 2 mg, and 3 mg

DOSE & ADMINISTRATION

- Recommended dosage of Loreev XR® is equal to the total daily dose of lorazepam tablets (at the previous three times daily dosage).
- Administer Loreev XR® orally once daily in the morning.
- Capsules may be swallowed whole or opened and the entire contents sprinkled onto applesauce. Do not crush or chew.
- For dosage adjustments, discontinue Loreev XR® and switch to lorazepam tablets to adjust dosage.

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EFFICACY

The effectiveness of lorazepam in long-term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should periodically reassess the usefulness of the drug for the individual patient.