

FIRST TIME GENERIC APPROVAL

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| Brand Name | Viibryd™ |
| Generic Name | vilazodone hydrochloride |
| Drug Manufacturer | Alembic Pharms Ltd. |

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

January 10, 2020

LAUNCH DATE

June 6, 2022

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 208202

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Vilazodone is indicated for the treatment of major depressive disorder (MDD) in adults.

MECHANISMS OF ACTION

The mechanism of action of vilazodone in the treatment of major depressive disorder is not fully understood but is thought to be related to its enhancement of serotonergic activity in the CNS through selective inhibition of serotonin reuptake. Vilazodone is also a partial agonist at serotonergic 5-HT_{1A} receptors; however, the net result of this action on serotonergic transmission and its role in vilazodone's antidepressant effect are unknown.

DOSE FORM AND STRENGTH

Tablets: 10 mg, 20 mg, and 40 mg

DOSE & ADMINISTRATION

- Recommended target dosage: 20 mg to 40 mg once daily with food.
- To titrate: start with initial dosage of 10 mg once daily for 7 days, followed by 20 mg once daily. The dose may be increased up to 40 mg once daily after a minimum of 7 days between dosage increases.
- Prior to initiating vilazodone, screen for bipolar disorder.
- When discontinuing vilazodone, reduce dosage gradually.

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