

## CLINICAL UPDATE

<b>Brand Name</b>	Citalopram
<b>Generic Name</b>	citalopram
<b>Drug Manufacturer</b>	Almatica Pharma LLC

### Clinical Update

#### TYPE OF CLINICAL UPDATE

New Dosage Form/New Strength

#### FDA APPROVAL DATE

January 31, 2022

#### LAUNCH DATE

February 22, 2022

#### REVIEW DESIGNATION

Standard

#### TYPE OF REVIEW

Type 2 - New Active Ingredient; Type 3 - New Dosage Form; New Drug Application (NDA): 215428

#### DISPENSING RESTRICTIONS

N/A

### Overview

#### INDICATION(S) FOR USE

Citalopram Capsules is a selective serotonin reuptake inhibitor (SSRI) indicated for treatment of Major Depressive Disorder (MDD) in adults.

#### MECHANISMS OF ACTION

The mechanism of action of citalopram as an antidepressant is unclear but is presumed to be related to potentiation of serotonergic activity in the central nervous system (CNS) resulting from its inhibition of CNS neuronal reuptake of serotonin (5-HT).

#### DOSAGE FORM(S) AND STRENGTH(S)

Capsules: 30 mg

#### DOSE & ADMINISTRATION

- Do not initiate treatment with Citalopram Capsules. Use another citalopram product for initial dosage titration or dosages other than 30 mg once daily.
- Administer once daily with or without food.
- Recommended dosage of Citalopram Capsules is 30 mg once daily.
- Citalopram dosages above 40 mg once daily are not recommended due to the risk of QT prolongation.

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- When discontinuing Citalopram Capsules, reduce dose gradually. Gradual dosage reduction will require use of another citalopram product.

## EFFICACY

The efficacy of Citalopram Capsules for the treatment for major depressive disorder (MDD) in adult patients is based upon adequate and well-controlled studies of another citalopram product. The results of these adequate and well-controlled studies of citalopram are presented below.

The efficacy of citalopram was established in two placebo-controlled studies (of 4 to 6 weeks in duration) in adult outpatients (ages 18-66) meeting DSM-III or DSM-III-R criteria for major depression (Studies 1 and 2).

Study 1, a 6-week trial in which patients received fixed citalopram doses of 10 mg, 20 mg, 40 mg, and 60 mg daily, showed that citalopram at doses of 40 mg and 60 mg daily (1.5 times the maximum recommended daily dosage of citalopram) was effective as measured by the Hamilton Depression Rating Scale (HAMD) total score, the primary efficacy endpoint. The HAMD-17 is a 17-item, clinician-rated scale used to assess severity of depressive symptoms. Scores on the HAMD-17 range from 0 to 52, with higher scores indicating more severe depression. This study showed no clear effect of the 10 mg and 20 mg daily doses, and the 60 mg daily dose was not more effective than the 40 mg daily dose. Due to the risk of QTc prolongation and ventricular arrhythmias, the maximum recommended dosage of citalopram is 40 mg once daily.

In study 2, a 4-week, placebo-controlled trial in patients with MDD, the initial dose was 20 mg daily, followed by titration to the maximum tolerated dose or a maximum dose of 80 mg daily (2 times the recommended daily dosage of citalopram). Patients treated with citalopram showed significantly greater improvement than placebo patients on the HAMD total score, the primary efficacy endpoint. In three additional placebo-controlled trials in patients with MDD, the difference in response to treatment between patients receiving citalopram and patients receiving placebo was not statistically significant.

In two long-term studies, patients with MDD who had responded to citalopram during an initial 6 or 8 weeks of acute treatment were randomized to continuation of citalopram or placebo. In one study, patients received fixed doses of citalopram 20 mg or 40 mg daily and in the second study, patients received flexible doses of citalopram 20 mg to 60 mg daily (1.5 times the maximum recommended daily dosage for citalopram). In both studies, patients receiving continued citalopram treatment experienced statistically significantly lower relapse rates over the subsequent 6 months compared to those receiving placebo. In the fixed-dose study, the decreased rate of depression relapse was similar in patients receiving 20 mg or 40 mg daily of citalopram. Due to the risk of QTc prolongation and ventricular arrhythmias, the maximum recommended dosage of citalopram is 40 mg once daily.