



SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Escitalopram Tablets

ASCIPRAM 10/20

2. QUALITATIVE AND QUANTITAVE COMPOSITION

Each Film coated Tablet contains

Escitalopram Oxalate USP equivalent to Escitalopram.....10 mg

Escitalopram Oxalate USP equivalent to Escitalopram.....20 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film coated tablets

Ascipram 10

Light Pink coloured, circular, biconvex, film-coated tablets 'MICRO' engraved on one surface and Breakline on other surface.

Ascipram 20

Orange coloured, circular, biconvex, film-coated 'MICRO' engraved on one surface and Breakline on other surface.

Breakline is to facilitate breaking for ease of swallowing and not for dividing into equal doses.

MICRO LABS LIMITED, INDIA
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4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of major depressive episodes

Treatment of panic disorder with or without agoraphobia

Treatment of social anxiety disorder (social phobia)

Treatment of generalized anxiety disorder

Treatment of obsessive-compulsive disorder

4.2 Posology and method of administration

Posology

Safety of daily doses above 20 mg has not been demonstrated.

Major depressive episodes

Usual dosage is 10 mg once daily. Depending on individual patient response, the dose may be increased to a maximum of 20 mg daily.

Usually 2-4 weeks are necessary to obtain antidepressant response. After the symptoms resolve, treatment for at least 6 months is required for consolidation of the response.

Panic disorder with or without agoraphobia

An initial dose of 5 mg is recommended for the first week before increasing the dose to 10 mg daily. The dose may be further increased, up to a maximum of 20 mg daily, dependent on individual patient response.

Maximum effectiveness is reached after about 3 months. The treatment lasts several months.

Social anxiety disorder

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Usual dosage is 10 mg once daily. Usually 2-4 weeks are necessary to obtain symptom relief. The dose may subsequently, depending on individual patient response, be decreased to 5 mg or increased to a maximum of 20 mg daily.

Social anxiety disorder is a disease with a chronic course, and treatment for 12 weeks is recommended to consolidate response. Long-term treatment of responders has been studied for 6 months and can be considered on an individual basis to prevent relapse; treatment benefits should be re-evaluated at regular intervals.

Social anxiety disorder is a well-defined diagnostic terminology of a specific disorder, which should not be confounded with excessive shyness. Pharmacotherapy is only indicated if the disorder interferes significantly with professional and social activities.

The place of this treatment compared to cognitive behavioral therapy has not been assessed. Pharmacotherapy is part of an overall therapeutic strategy.

Generalized anxiety disorder

Initial dosage is 10 mg once daily. Depending on the individual patient response, the dose may be increased to a maximum of 20 mg daily.

Long-term treatment of responders has been studied for at least 6 months in patients receiving 20 mg daily. Treatment benefits and dose should be re-evaluated at regular intervals (see Section 5.1).

Obsessive-compulsive disorder

Initial dosage is 10 mg once daily. Depending on the individual patient response, the dose may be increased to a maximum of 20 mg daily.

As OCD is a chronic disease, patients should be treated for a sufficient period to ensure that they are symptom free.

Treatment benefits and dose should be re-evaluated at regular intervals (see section 5.1).

Elderly patients (> 65 years of age)

Initial dosage is 5 mg once daily. Depending on individual patient response the dose may be increased to 10 mg daily (see section 5.2).