Artwork No: AW/I216E/01
Type: Package Insert
Size: 180 x 120 mm
Prepared date: 09-12-2025

ESCITALOPRAM

SEROPRAM 5®

5 mg Film coated tablet
Antidepressant

PRODUCT DESCRIPTION:
Pink coloured, round, biconvex, film coated tablet.

FORMULATION/COMPOSITION:
Each film-coated tablet contains:
Escitalopram Oxalate equivalent to Escitalopram.....5 mg

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

DOSAGE AND ADMINSTRATION:

Safety of daily doses above 20 mg has not been demonstrated.
Escitalopram is administered as a single daily dose and may be taken with or without food.

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
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 symptom relief. Treatment for 3 months is recommended to consolidate response. Long-term treatment of responders for 6 months has been shown to prevent relapse and can be considered on an individual basis; treatment benefits should be re-evaluated at regular intervals.

Generalized anxiety disorder
Usual dosage is 10 mg once daily. Depending on individual patient response, the dose may be increased to a maximum of 20 mg daily. Treatment for 3 months is recommended to consolidate response. Long-term treatment of responders for 6 months has been shown to prevent relapse and can be considered on an individual basis; treatment benefits should be reevaluated at regular intervals.

Obsessive-compulsive disorder (OCD)
Usual dosage is 10 mg once daily. Depending on individual patient response, the dose may be increased to 20 mg daily. Long-term treatment of patients responding to a 16-week open treatment phase has been studied for at least 24 weeks in patients receiving 10 or 20 mg/day. As OCD is a chronic disease, patients should be treated for a sufficient period to ensure that they are symptom free. This period may be several months or even longer.

Elderly patients (> 65 years of age)
Initial treatment with half the usually recommended dose and a lower maximum dose should be considered

Children and adolescents (<18 years)
Escitalopram should not be used in the treatment of children and adolescents under the age of 18 years, see special warning and special precaution for use.

Reduced renal function
Dosage adjustment is not necessary in patients with mild or moderate renal impairment. Caution is advised in patients with severely reduced renal function (CLCR less than 30 ml/min).

Reduced hepatic function
An initial dose of 5 mg daily for the first two weeks of treatment is recommended. Depending on individual patient response, the dose may be increased to 10 mg daily.

Discontinuation symptoms
When stopping treatment with escitalopram, the dose should be gradually reduced over a period of at least one to two weeks in order to avoid possible discontinuation symptoms.

CONTRAINDICATIONS:
Hypersensitivity to the active ingredient or any excipients

SPECIAL WARNING AND PRECAUTIONS:
General
Antidepressants should not be used in the treatment of children and adolescents under age of 18 years. Suicide related behaviours (suicide attempt and suicidal thoughts), and hostility (predominantly aggression, oppositional behaviour and anger) were more frequently observed in clinical trials among children and adolescents treated with antidepressants compared to those treated with placebo. If, based on clinical need, a decision to treat is nevertheless taken, the patient should be carefully monitored for the appearance of suicidal symptoms

The following special warnings and precautions apply to the therapeutic class of SSRIs (Selective Serotonin Re-uptake Inhibitors).

Paradoxical anxiety
Some patients with panic disorder may experience increased anxiety symptoms at the beginning of treatment with antidepressants. This paradoxical reaction usually subsides within the first two weeks of treatment. A low starting dose is advised to reduce the likelihood of an anxiogenic effect

Seizures
Escitalopram should be discontinued if a patient develops seizures for the first time, or if there is an increase in seizure frequency (in patients with a previous diagnosis of epilepsy). SSRIs should be avoided in patients with unstable epilepsy, and patients with controlled epilepsy should be closely monitored.

Mania
SSRIs should be used with caution in patients with a history of mania/hypomania. SSRIs should be discontinued in any patient entering a manic phase.

Diabetes
In patients with diabetes, treatment with an SSRI may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.

Suicide/suicidal thoughts or clinical worsening
Depression is associated with an increased risk of suicidal thoughts, self-harm and suicide (suicide-related events). This risk persists until significant remission occurs. As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs.

Akathisia/psychomotor restlessness
The use of SSRIs/SNRIs has been associated with the development of akathisia, characterised by a subjectively unpleasant or distressing restlessness and need to move often accompanied by an inability to sit or stand still. This is most likely to occur within the first few weeks of treatment. In patients who develop these symptoms, increasing the dose may be detrimental.

Hyponatraemia
Hyponatraemia, probably due to inappropriate antidiuretic hormone secretion (SIADH), has been reported rarely with the use of SSRIs and generally resolves on discontinuation of therapy. Caution should be exercised in patients at risk, such as the elderly, or patients with cirrhosis, or if used in combination with other medications which may cause hyponatraemia

Haemorrhage
There have been reports of cutaneous bleeding abnormalities, such as ecchymoses and

purpura, with SSRIs. SSRIs/SNRIs may increase the risk of postpartum haemorrhage. Caution is advised in patients taking SSRIs, particularly with concomitant use of oral anticoagulants; medicinal products known to affect platelet function (e.g. atypical antipsychotics and phenothiazines, most tricyclic antidepressants, acetylsalicylic acid and non-steroidal anti-inflammatory medicinal products (NSAIDs), ticlopidine and dipyridamole); and in patients with known bleeding tendencies. ECT (electroconvulsive therapy) There is limited clinical experience of concurrent administration of SSRIs and ECT; therefore, caution is advisable

PREGNANCY AND LACTATION

Pregnancy

Limited clinical data are available regarding exposure to escitalopram during pregnancy. Animal studies have shown reproductive toxicity.

Escitalopram should not be used during pregnancy unless clearly needed and after careful consideration of the risk/ benefit ratio.

Lactation

It is expected that escitalopram will be excreted into human milk and breast-feeding is not

recommended during the treatment.

Fertility

Animal data have shown that some SSRIs may affect sperm quality. Human case reports with some SSRIs have shown that an effect on sperm quality is reversible. Impact on human fertility has not been observed so far.

ADVERSE REACTIONS:

Blood and lymphatic system disorders:
Thrombocytopenia
Immune system disorders:
Anaphylactic reaction
Endocrine disorders:
Inappropriate ADH secretion
Metabolism and nutrition disorders:
Decreased appetite, increased appetite, weight increased, Weight decreased, Hyponatraemia, anorexia Psychiatric disorders:
Anxiety, restlessness, abnormal dreams
Female and male: libido decreased
Female: anorgasmia, Bruxism, agitation, nervousness, panic attack, confusional state, Aggression, depersonalisation, hallucination, Mania, suicidal ideation, suicidal behaviour
Nervous system disorders: Insomnia, somnolence, dizziness, paraesthesia, tremor, Taste disturbance, sleep disorder, syncope, Serotonin syndrome, Dyskinesia, movement disorder, convulsion, psychomotor restlessness/akathisia
Eye disorders: Mydriasis, visual disturbance
Ear and labyrinth disorders: Tinnitus
Cardiac disorders: Tachycardia, Bradycardia, Electrocardiogram QT prolonged. Vascular disorders: Orthostatic hypotension
Respiratory, thoracic and mediastinal disorders: Sinusitis, yawning, Epistaxis
Gastrointestinal disorders: Nausea, Diarrhoea, constipation, vomiting, dry mouth, Gastrointestinal haemorrhages (including rectal haemorrhage) Hepatobiliary disorders: Hepatitis, liver function test abnormal
Skin and subcutaneous tissue disorders: Sweating increased, Urticaria, alopecia, rash, pruritus, Ecchymosis, angioedemas
Musculoskeletal and connective tissue disorders: Arthralgia, myalgia
Renal and urinary disorders: Urinary retention
Reproductive system and breast disorders:
Male: ejaculation disorder, impotence
Female: metrorrhagia, Menorrhagia Galactorrhoea Male: priapism
General disorders and administration site conditions: Fatigue, pyrexia, Oedema

OVERDOSE

Symptoms

Symptoms seen in reported overdose of escitalopram include symptoms mainly related to the central nervous system (ranging from dizziness, tremor, and agitation to rare cases of serotonin syndrome, convulsion, and coma), the gastrointestinal system (nausea/vomiting), and the cardiovascular system (hypotension, tachycardia, QT prolongation, and arrhythmia) and electrolyte/fluid balance conditions (hypokalaemia, hyponatraemia).

Treatment

There is no specific antidote. Establish and maintain an airway, ensure adequate oxygenation and respiratory function. Gastric lavage and the use of activated charcoal should be considered. Gastric lavage should be carried out as soon as possible after oral ingestion. Cardiac and vital signs monitoring are recommended along with general symptomatic supportive measures.

PHARMACOLOGICAL PROPERTIES:

Pharmacodynamic properties:

Pharmacotherapeutic group: antidepressants, selective serotonin reuptake inhibitor
ATC-code: N 06 AB 10

Mechanism of action

Escitalopram is a selective inhibitor of serotonin (5-HT) re-uptake with high affinity for the primary binding site. It also binds to an allosteric site on the serotonin transporter, with a 1000-fold lower affinity. Allosteric modulation of the serotonin transporter enhances binding of escitalopram to the primary binding site, resulting in more complete serotonin reuptake inhibition. Escitalopram has no or low affinity for a number of receptors including 5 HT1A, 5 HT2, DA D1 and D2 receptors, α1-, α2-, β-adrenoceptors, histamine H1, muscarine cholinergic, benzodiazepine, and opioid receptors. The inhibition of 5-HT re-uptake is the only likely mechanism of action explaining the pharmacological and clinical effects of escitalopram.

Pharmacokinetic properties:

Absorption

Absorption is almost complete and independent of food intake. Mean time to maximum concentration (mean Tmax) is 4 hours after multiple dosing. As with racemic citalopram, the absolute bio-availability of escitalopram is expected to be about 80%.

Distribution

The apparent volume of distribution (Vd,β/F) after oral administration is about 12 to 26 L/kg. The plasma protein binding is below 80% for escitalopram and its main metabolites.

Biotransformation

Escitalopram is metabolised in the liver to the demethylated and didemethylated metabolites. Both of these are pharmacologically active. Alternatively, the nitrogen may be oxidised to form the N-oxide metabolite. Both parent substance and metabolites are partly excreted as glucuronides. After multiple dosing the mean concentrations of the demethyl and didemethyl metabolites are usually 28-31%.

Elimination

The elimination half-life (t½ β) after multiple dosing is about 30 hours and the oral plasma clearance (Cloral) is about 0.6 L/min. The major metabolites have a significantly longer half-life. Escitalopram and major metabolites are assumed to be eliminated by both the hepatic (metabolic) and the renal routes, with the major part of the dose excreted as metabolites in the urine.

STORAGE CONDITION:

Store at or below 30°C

AVAILABILITY:

Alu-Alu Strip pack x 10's (Box of 100's)

MANUFACTURED BY:

Quest Pharmaceuticals Pvt. Ltd.
Chhatapipara, Bara, Nepal

MARKETING AUTHORIZATION HOLDER:

Quest Pharmaceuticals Pvt. Ltd.
Daan Sadan, Teku, Kathmandu, Nepal