Estly

[Escitalopram]
5mg, 10mg & 20mg Tablets

ایسٹلی

۵ ملی گرام، ۱۰ ملی گرام اور ۲۰ ملی گرام گولیاں

DESCRIPTION:
ESTLY (Escitalopram), a potent selective serotonin reuptake inhibitor (SSRI) is the pure S-enantiomer (single isomer) of the racemic bicyclic phthalane derivative citalopram.
QUALITATIVE AND QUANTITATIVE COMPOSITION:
ESTLY (Escitalopram) is available for oral administration as:

1. ESTLY 5mg Tablet
Each film coated tablet contains:
Escitalopram (as escitalopram oxalate USP)... 5mg
(Product Specs.: USP)

2. ESTLY 10mg Tablet
Each film coated tablet contains:
Escitalopram (as escitalopram oxalate USP)... 10mg
(Product Specs.: USP)

3. ESTLY 20mg Tablet
Each film coated tablet contains:
Escitalopram (as escitalopram oxalate USP)... 20mg
(Product Specs.: USP)

CLINICAL PHARMACOLOGY:
Mechanism of Action:
The antidepressant action of escitalopram resulting from its inhibition of CNS neuronal reuptake of serotonin (5-HT).
Pharmacokinetics:
Absorption:
Absorption is almost complete and independent of food intake (mean tmax is 4 hours after multiple dosing). The absolute bioavailability is 80%.
Distribution:
The apparent volume of distribution after oral administration is about 12 to 26L/kg. The binding of escitalopram to human plasma proteins is approximately 56%.
Metabolism:
Biotransformation of escitalopram to the demethylated metabolite is mediated primarily by CYP2C19. Some contribution by the enzymes CYP3A4 and CYP2D6 is possible.
Excretion:
The elimination half-life after multiple dosing is about 30 hours. 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.
Special Populations:
Elderly Patients (>65 years):
Escitalopram AUC and half-life were increased in elderly subjects, and Cmax was unchanged.
Hepatic Insufficiency:
In patients with mild or moderate hepatic impairment the half-life of escitalopram was about twice.
Renal Insufficiency:
Longer half-life and a minor increase in exposure have been observed in patients with reduced kidney function.
INDICATIONS:
ESTLY (Escitalopram) is indicated for the treatment of:
- Major depressive disorder
- Panic disorder with or without agoraphobia
- Social anxiety disorder (social phobia)
- Generalized anxiety disorder
- Obsessive-compulsive disorder

DOSAGE AND ADMINISTRATION:
ESTLY (Escitalopram) is administered as a single daily dose and may be taken with or without food.

Indication	Initial Dose	Maximum Dose	Frequency	Symptom Relief	Maintenance Treatment
Major depressive disorder					
Adolescents (12 to 17 years of age)	10mg OD	20mg OD*	Increased 20 mg after 3 week treatment with 10mg	-	-
Adult	10mg OD	20mg OD*	Increased 20 mg after 1 week treatment with 10mg	2-4 weeks	6 months
Panic disorder with or without agoraphobia	5mg OD	20mg OD*	Increasing the dose gradually after 1 week treatment according to available strength	3 months	Several months
Social anxiety disorder	10mg OD	20mg OD*	gradually decreased to 5mg or increased to a maximum of 20mg	2-4 weeks	6 months
Generalised anxiety disorder	10mg OD	20mg OD*	-	-	6 months
Obsessive-compulsive disorder (OCD)	10mg OD	20mg OD*	-	-	Sufficient period to ensure that patients are symptom free

* Dose may be increased according to the individual patient response.
Special Populations:
Elderly Patients (>65 years of age):
Initial dosage is 5mg once daily. Depending on individual patient response the dose may beincreased to 10mg daily.
Patients with Renal Impairment:
Caution is advised in patients with severely reduced renal function (CLCR less than 30mL/min.).
Patients with Hepatic Impairment:
An initial dose of 5mg daily for the first two weeks of treatment is recommended in patients with mild to moderate hepatic impairment. Depending on individual patient response, the dose may be increased to 10mg daily. Caution and extra careful dose titration is advised in patients with severely reduced hepatic function.
Discontinuation:
When stopping treatment with **ESTLY** the dose should be gradually reduced over a period of at least one or two weeks in order to reduce the risk of discontinuation symptoms.

CONTRAINDICATIONS:
Escitalopram is contraindicated:
- In patients with hypersensitivity to escitalopram or to any of the component
- To use concomitantly with non-selective, irreversible monoamine oxidase inhibitors (MAO-inhibitors) due to the risk of serotonin syndrome
- To use concomitantly with reversible MAO-A inhibitors (e.g. moclobemide) or the reversible non-selective MAO-inhibitor linezolid due to the risk of serotonin syndrome
- In patients with known QT interval prolongation or congenital long QT syndrome
- To use concomitantly with drugs that are known to prolong the QT interval.

PRECAUTIONS:

WARNINGS: SUICIDALITY AND ANTIDEPRESSANT DRUGS Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. **ESTLY** is not approved for use in pediatric patients less than 12 years of age.

Use **ESTLY** with caution in; patients with controlled epilepsy, patients with a history of mania/ hypomania, patients with coronary heart disease
Discontinued **ESTLY** if, patient develops seizures, increase in seizure frequency, patients with unstable epilepsy, patient entering a manic phase, signs of cardiac arrhythmia occur during treatment, patients develop serotonin syndrome when using **ESTLY** concomitantly with serotonergic medicinal products. If this occurs treatment with the **ESTLY** and the serotonergic medicinal product should be discontinued.
- Some patients with panic disorder may experience increased anxiety symptoms at the beginning of treatment. A low starting dose is advised
- In patients with diabetes, SSRI may alter glycemic control. Insulin and/or oral hypoglycemic dosage may need to be adjusted
- **ESTLY** has been found to cause a dose-dependent prolongation of the QT interval. If patients with stable cardiac disease are treated, an ECG review should be considered before treatment is started.

Pregnancy:
ESTLY should not be used during pregnancy unless clearly necessary.
Lactation:
Contraindicated during lactation.
DRUG INTERACTIONS:
- Caution is advised concomitantly with **oral anticoagulants** and drugs known to **affect platelet function** e.g. atypical antipsychotics, phenothiazines, tricyclic antidepressants, acetylsalicylic acid and NSAIDs, ticlopidine, dipyridamole and in patients with known bleeding tendencies
- Coadministration with **serotonergic drugs** (e.g. Tramadol, sumatriptan and other triptans) may lead to an enhancement of serotonergic effects Caution is advised when SSRIs is concomitantly administered with **drugs capable of lowering the seizure threshold** e.g. antidepressants (tricyclics, SSRIs), neuroleptics - (phenothiazines, thioxanthenes and butyroph enones), mefloquine, bupropion and tramadol.
- **Lithium/Tryptophan,** enhanced effects of SSRIs when use concomitantly
- **Other centrally acting drugs** use with caution concomitantly with SSRIs
- Concomitant use of SSRIs and herbal remedies containing **St. John's Wort** (Hypericum preforatum) may result in an increased incidence of adverse reactions
- Coadministration of **ESTLY** with **CYP2C19 inhibitors** (e.g. omeprazole, esomeprazole, fluvoxamine, lansoprazole, ticlopidine) or cimetidine resulted in an increase of plasma concentrations of escitalopram. Therefore, caution is advised and a reduction in the dose of escitalopram may be necessary
- Escitalopram is an **inhibitor of CYP2D6.** Caution is recommended when escitalopram is coadministered with drugs that are mainly metabolised by CYP2D6 such as desipramine, clomipramine, nortryptyline, risperidone, thioridazine and haloperidol and that have a narrow therapeutic index e.g. flecainide, propafenone and metoprolol. Dosage adjustment may be warranted.

ADVERSE EFFECTS:
Very Common: Nausea.
Common: Decreased appetite, increased appetite, weight increased, anxiety, abnormal dreams, insomnia, dizziness, tremor, diarrhea, constipation, vomiting, dry mouth, sweating increased, myalgia and ejaculation disorder.
Uncommon: Panic attack, sleep disorder, visual disturbance, tinnitus, tachycardia, gastrointestinal hemorrhages.
Rare: Anaphylactic reaction, serotonin syndrome.
Withdrawal Symptoms: Dizziness, sensory disturbances, sleep disturbances (including insomnia and intense dreams), anxiety, nausea, vomiting, tremor, headache, diarrhea, palpitations, emotional instability, and visual disturbances.
OVERDOSAGE:
Symptoms:
Dizziness, tremor, agitation, serotonin syndrome, convulsion, coma, nausea/vomiting, hypotension, tachycardia, QT interval prolongation, arrhythmia hypokalemia and hyponatremia.
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. Cardiac, vital signs and ECG monitoring are recommended along with general symptomatic supportive measures.
INSTRUCTIONS:
- Store below 30°C
- Protect from light & moisture
- Keep out of reach of children

To be sold on prescription of a registered medial practitioner.
HOW SUPPLIED:
ESTLY (Escitalopram) 5mg Tablets are available in pack of 2×7's.
ESTLY (Escitalopram) 10mg Tablets are available in pack of 2×7's.
ESTLY (Escitalopram) 20mg Tablets are available in pack of 2×7's.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایت: دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

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