For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

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Escitalopram & Clonazepam Tablets IP

Exínus® Plus एक्सिनस प्लस

WARNING: SUICIDALITY AND ANTIDEPRESSANT DRUGS:
Antidepressant drugs increased the risk, compared to placebo, of suicidal thinking and behaviour (suicidality) in children, adolescents and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of EXINUS PLUS or any other antidepressant in a child, adolescent or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants, compared to placebo, in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 years and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. 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 behaviour. Families and caregivers should be advised about the need for close observation and communication with the prescriber EXINUS PLUS is not approved for use in paediatric patients less than 12 years of age.

COMPOSITION :
Each film coated tablet contains
Escitalopram Oxalate IP
Equivalent to Escitalopram 10 mg
Clonazepam IP 0.5 mg
Excipients q.s.
Colours : Ferric Oxide Yellow USP-NF and Titanium Dioxide IP

INDICATIONS : EXINUS PLUS Tablets are indicated for the treatment of patients with comorbid depression and anxiety disorder

DOSAGE : The recommended dose of escitalopram is 10 mg/day in adults. The dose should not be increased considering the presence of clonazepam.
Initial dose of clonazepam is 0.5 mg/day in the initial stages of treatment. Dosage of clonazepam should not exceed 1 mg/day.

CONTRAINDICATIONS :
- Hypersensitivity to drug
- Acute angle glaucoma
- Concomitant use of monoamine oxidase inhibitors (MAOIs)
- Concomitant use in patients taking pimozide.
- In patients with clinical or biochemical evidence of significant liver disease.

WARNINGS AND PRECAUTIONS : Clinical Worsening and Suicide Risk
Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Prescriptions for the tablets should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.
Screening Patients for Bipolar Disorder : A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. It should be noted that EXINUS PLUS Tablets is not approved for use in treating bipolar depression.
Activation of Mania/Hypomania : It should be used cautiously in patients with a history of mania and should be discontinued in any patient entering the manic phase.
Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like Reactions
The development of a potentially life-threatening serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions have been reported with SNRIs and SSRIs alone, including escitalopram treatment, but particularly with concomitant use of serotonergic drugs (including triptans) with drugs which impair metabolism of serotonin (including MAOIs), or with antipsychotics or other dopamine antagonists.
Seizures : Although clonazepam has anticonvulsant properties, escitalopram has not been systematically evaluated in patients with a seizure disorder. When used in patients in whom several different types of seizure disorders coexist, clonazepam may increase the incidence or precipitate the onset of generalized tonic-clonic seizures (grand mal).It should be introduced with care in patients with a history of seizure disorder.
Hyponatremia: Discontinuation of EXINUS PLUS Tablets should be considered in patients with symptomatic hyponatremia and appropriate medical intervention should be instituted. Signs and symptoms of hyponatremia include headache, difficulty concentrating, memory impairment, confusion, weakness and unsteadiness, which may lead to falls. Signs and symptoms associated with more severe and/or acute cases have included hallucination, syncope, seizure, coma, respiratory arrest and death.
Abnormal Bleeding: Caution is advised in patients taking EXINUS PLUS Tablets, particularly in concomitant use with oral anticoagulants. Interference with Cognitive and Motor Performance. They should also be warned about the concomitant use of alcohol or other CNS-depressant drugs during therapy.

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 two weeks during continued treatment. A low starting dose is advised to reduce the likelihood of an anxiogenic effect.
Patients suffering from Closed-Angle Glaucoma, Respiratory Disorders, Liver Disease and obesity should exercise caution.
Tablets are excreted by the kidneys; to avoid their excess accumulation, caution should be exercised in the administration of the drug to patients with impaired hepatic and renal function.
Discontinuation : A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered.

SIDE EFFECTS : Common side effects include delayed ejaculation, confusion, vomiting, memory impairment, drowsiness, tiredness, anorgasmia, low sexual desire, nausea, diarrhea, uncoordinated body movement, fatigue and memory impairment.

DRUG INTERACTIONS : The drug should not be used in combination with Atenolol and Codeine. Carbamazepine, rifampin, rifabutin may enhance the metabolism of clonazepam and decrease its therapeutic effect; consider using an alternative sedative/hypnotic agent.
Cimetidine, ciprofloxacin, clarithromycin, clozapine, CNS depressants, diltiazem, disulfiram, digoxin, erythromycin, ethanol, fluconazole, fluoxetine, fluvoxamine, grapefruit juice, isoniazid, itraconazole, ketoconazole, labetalol, levodopa, loxapine, metoprolol, metronidazole, miconazole, nefazodone, omeprazole, phenytoin, rifabutin, rifampin, troleandomycin, verapamil may increase the serum level and/or toxicity of clonazepam; monitor for altered benzodiazepine response.

PREGNANCY : When treating a pregnant woman, the physician should carefully consider both the potential risks and benefits of treatment. Administration of high doses in the last trimester of pregnancy or during labour can cause irregularities in the heart beat of the unborn child and hypothermia, hypotonia, mild respiratory depression and poor sucking in the neonate. Therefore it should not be used in pregnancy unless necessary.

LACTATION : Escitalopram and clonazepam is excreted in human breast milk. Caution should be exercised and breastfeeding infants should be observed for adverse reactions when tablets are administered to a lactating mother.

PEDIATRIC USE : It should not be used in the treatment of children and adolescents below the age of 12 years.

GERIATRIC USE : SSRIs and SNRIs, including escitalopram, have been associated with cases of clinically significant hyponatremia in elderly patients, who may be at greater risk for this adverse event. Clonazepam is also advised to be used with caution; therefore EXINUS PLUS Tablets should be used with caution in this patient population.Sedating drugs may cause confusion and over-sedation in the elderly; elderly patients generally should be started on low doses and observed closely.

OVERDOSAGE : Symptoms most often accompanying escitalopram overdose, a or in combination with other drugs and/or alcohol, include 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), gastrointestinal system (nausea, vomiting) and the cardiovascular system (hypotension, tachycardia, QT prolongation, arrhythmia, and very rare cases of torsade de pointes) and electrolyte/fluid balance conditions (hypokalaemia, hyponatraemia) and sleep disturbances (insomnia somnolence). Acute renal failure has been very rarely reported accompanying overdose. In case of clonazepam, symptoms of overdosage are like those produced by other CNS depressants i.e., somnolence, confusion, coma and diminished reflexes.

Storage :
Store in a dry place below 30°C, protect from light and moisture.
Keep medicines out of reach of children

Presentation :
Box containing 10 x 10's tablets or as required

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Manufactured by : **Swiss Garnier Biotech Pvt. Ltd.**
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Marketed by :

JAYURANCE
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