

FELIZ S PLUS

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

Abbreviated Prescribing information for FELIZ S PLUS (Escitalopram Oxalate and Clonazepam Tablets I.P)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Clonazepam, is believed to act via its ability to enhance the activity of gamma aminobutyric acid (GABA), the major inhibitory neurotransmitter in the central nervous system. **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. Escitalopram has no or low affinity for a number of receptors including 5-HT_{1A}, 5-HT₂, DA D₁ and D₂ receptors, α ₁-, α ₂-, 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.

DOSAGE AND ADMINISTRATION: Dosage should be taken as directed by your Physician.

CONTRAINDICATION: Hypersensitivity to the active substance (Clonazepam and Escitalopram). History of sensitivity to benzodiazepines or any of the excipients. Clinical or biochemical evidence of significant liver disease. Acute narrow angle glaucoma (it may be used in patients with open angle glaucoma who are receiving appropriate therapy). Concomitant treatment with non-selective, irreversible monoamine oxidase inhibitors (MAO-inhibitors) is contraindicated due to the risk of serotonin syndrome with agitation, tremor, hyperthermia etc. The combination of Escitalopram Oxalate and Clonazepam tablets with reversible MAO-A inhibitors (e.g. moclobemide) or the reversible non-selective MAO-inhibitor linezolid is contraindicated due to the risk of onset of a serotonin syndrome. Contraindicated in patients with known QT interval prolongation or congenital long QT syndrome, with medicinal products that are known to prolong the QT interval, Acute pulmonary insufficiency; severe respiratory insufficiency, sleep apnoea syndrome, myasthenia gravis, severe hepatic insufficiency. Must not be used in patients in a coma, or in patients known to be abusing pharmaceuticals, drugs or alcohol.

WARNINGS & PRECAUTIONS: Warnings: Clinical Worsening and Suicide Risk, Risks from Concomitant Use with Opioids may result in in profound sedation, respiratory depression, coma, and death. Precautions: Worsening of Seizures, Laboratory Testing During Long-Term Therapy, Psychiatric and Paradoxical Reactions, Risks of Withdrawal, Hypersalivation, Respiratory Depression, Porphyria, Paradoxical anxiety, Seizures, Mania, Diabetes, Akathisia/psychomotor restlessness, Hyponatraemia, Haemorrhage, Serotonin syndrome, St. John's wort, Coronary heart disease, QT interval prolongation, Angle-Closure Glaucoma.

DRUGS INTERACTIONS: *Clonazepam:* Opioids: increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect, Alcohol: modify the effects of the drug, Antiepileptic drugs: sedation and apathy, and toxicity. *Escitalopram:* Pharmacodynamic interactions: Irreversible non-selective MAOIs, Reversible, selective MAO-A inhibitor (moclobemide), Reversible, non-selective MAO-inhibitor (linezolid), Irreversible, selective MAO-B inhibitor (selegiline), QT interval prolongation. Combinations requiring precautions for use: Serotonergic medicinal products, Medicinal products lowering the seizure threshold, Lithium, tryptophan, St. John's wort, Haemorrhage, Medicinal products inducing hypokalaemia/hypomagnesaemia, Etizolam. Pharmacokinetic interactions: Influence of other medicinal products on the pharmacokinetics of escitalopram: Omeprazole, cimetidine, esomeprazole, fluvoxamine, lansoprazole, ticlopidine. Effect of escitalopram on the

pharmacokinetics of other medicinal products: Flecainide, propafenone and metoprolol, desipramine.

ADVERSE REACTIONS: Blood Dyscrasias, anaphylaxis and angioedema, Anterograde amnesia, Depression, loss of libido, impotence, Dizziness, light-headedness, somnolence, fatigue, co-ordination disturbances, poor concentration, restlessness, confusion and disorientation, headache, Paradoxical effects such as aggressiveness, excitability, nervousness, hostility, anxiety, sleep disturbances, nightmares, vivid dreams, irritability, agitation, psychotic disorders and activation of new types of seizures, Double vision and nystagmus, Cardiac failure, nausea, gastrointestinal symptoms, urticaria, pruritus, transient hair loss, pigmentation changes, Muscle weakness, occasional muscular hypotonia, urinary incontinence, tremor, sweating, agitation, sleep disturbances and anxiety, headaches, muscle pain, extreme anxiety, tension, restlessness, confusion, irritability and epileptic seizures, Decreased appetite, Bruxism, agitation, nervousness, panic attack, confusional state, Taste disturbance, sleep disorder, syncope, Serotonin syndrome, Mydriasis, visual disturbance, Tachycardia, Bradycardia, Urticaria, alopecia, rash, pruritus, priapism, Thrombocytopenia, Decreased appetite, increased appetite, weight increased, anorexia, tinnitus, Epistaxis, Sinusitis, yawning, QT interval prolongation.

MARKETED BY:

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(Additional information is available on request)