

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)

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

PHARMACOLOGICAL PROPERTIES:

Clonazepam: Clonazepam exhibits pharmacological properties, which are common to benzodiazepines and include anticonvulsive, sedative, muscle relaxing and anxiolytic effects. *Escitalopram*: 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.

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS

Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death.

- Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

CONTRAINDICATION:

If you are allergic to clonazepam or any of the other ingredients of this medicine. If you are allergic to other benzodiazepine medicines and Escitalopram or any of the other ingredients of this medicine. Have significant liver disease, have an eye disease called acute narrow angle glaucoma, If you take other medicines which belongs to a group called MAO inhibitors, including selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression) and linezolid (an antibiotic), If you are born with or have had an episode of abnormal heart rhythm (Seen at ECG; an examination to evaluate how the heart is functioning), If you take medicines for heart rhythm problems or that may affect the heart's rhythm.

WARNINGS & PRECAUTIONS: Risks from Concomitant Use with Opioids, Interference with Cognitive and Motor Performance, Suicidal Behavior and Ideation. **PRECAUTIONS:** Worsening of Seizures, Laboratory Testing During Long-Term Therapy, Psychiatric and Paradoxical Reactions, Risks of Abrupt Withdrawal, Caution in Renally Impaired Patients, Hyper salivation, Respiratory Depression, Porphyria, Paediatric population, Paradoxical anxiety, Seizures, Mania, Diabetes, Suicide/suicidal thoughts or clinical worsening, Akathisia/psychomotor restlessness, Hyponatraemia, Haemorrhage, ECT (electroconvulsive therapy), Serotonin syndrome, St. John's wort, Coronary heart disease, QT interval prolongation, Angle-Closure Glaucoma.

DRUGS INTERACTIONS: *Clonazepam*: Opioids, Alcohol, Antiepileptic drugs, Pharmacokinetic interactions. *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, Serotonergic medicinal products, Medicinal products lowering the seizure threshold, Lithium, tryptophan, St. John's wort, Haemorrhage, Medicinal products inducing hypokalaemia/hypomagnesaemia. **Pharmacokinetic interactions:** Influence of other medicinal products on the pharmacokinetics of Escitalopram i.e. omeprazole, cimetidine, Effect of escitalopram on the pharmacokinetics of other medicinal products viz. flecainide, propafenone and metoprolol.

ADVERSE REACTIONS: Dyscrasias, anaphylaxis and angioedema, Anterograde amnesia, Depression, loss of libido, impotence, Dizziness, light-headedness, somnolence, fatigue, coordination 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.

MARKETED BY:

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IN/FELIZ S PLUS 5, 10 mg/DEC-20/02/ABPI

(Additional information is available on request)