FELIZ S LITE/CLONOTRIL PLUS

To be sold by retail on the prescription of a Registered Medical Practitioner only

Abbreviated Prescribing information for FELIZ S LITE/ CLONOTRIL PLUS [Escitalopram Oxalate and Clonazepam Tablets I.P.]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Escitalopram: 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. The inhibition of 5-HT re-uptake is the only likely mechanism of action explaining the pharmacological and clinical effects of escitalopram. **Clonazepam:** Clonazepam exhibits pharmacological properties which are common to benzodiazepines and include anticonvulsive, sedative, muscle relaxing and anxiolytic effects.

INDICATIONS: It is indicated for the treatment of patients with comorbid depression & anxiety disorders.

DOSAGE AND ADMINISTRATION: Escitalopram: 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 are resolved, treatment for at least 6 months is required for consolidation of the response. 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. In elderly patients (> 65 years of age) the initial dosage is 5 mg once daily. Depending on individual patient response the dose may be increased to 10 mg daily. **Clonazepam**: Initial dosage should not exceed 1 mg/day. The maintenance dosage for adults normally falls within the range 4 to 8 mg. For oral use. Take a single daily dose and may be taken with or without food. To ensure optimum dosage adjustment, children should be given the 0.5 mg tablets. Initial dosage should not exceed 0.25 mg/day for infants and small children (1 to 5 years) and 0.5 mg/day for older children and children aged 12 years and over

CONTRAINDICATION: Escitalopram: •Hypersensitivity to escitalopram or to any of the excipients. •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 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.• It is contraindicated in patients with known QT interval prolongation or congenital long QT syndrome. •It is contraindicated together with medicinal products that are known to prolong the QT interval. **Clonazepam:** •Known hypersensitivity to benzodiazepines •Hypersensitivity to the active substance or to any of the excipients. •Acute pulmonary insufficiency •Severe respiratory insufficiency •Sleep apnoea syndrome •Myasthenia gravis •Severe hepatic insufficiency •Clonazepam must not be used in patients in a coma, or in patients known to be abusing pharmaceuticals, drugs, or alcohol.

WARNINGS & PRECAUTIONS: Patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality. When used in patients in whom several different types of seizure disorders coexist, tablets may increase the incidence or precipitate the onset of generalized tonic-clonic seizures (grand mal). Periodic blood counts and liver function tests are advisable during long-term therapy. When discontinuing Escitalopram Oxalate and Clonazepam tablets, gradual withdrawal is essential. Caution should be exercised in the administration of the drug to patients with impaired renal function. It may cause respiratory depression and should be used with caution in patients with compromised respiratory function. It may have a porphyrogenic effect and should be used with care in patients with porphyria. SSRIs should be used with caution in patients with a history of mania/hypomania. In patients with diabetes, treatment with an SSRI may alter glycaemic control (hypoglycaemia or hyperglycaemia). Insulin and/or oral hypoglycaemic dosage may need to be adjusted. 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. 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. Escitalopram should therefore be used with caution in patients with angle-closure glaucoma or history of glaucoma.

DRUG INTERACTIONS: Escitalopram: It is contraindicated in combination with non-selective, irreversible MAOIs. Due to the risk of serotonin syndrome, the combination of escitalopram with a MAO-A inhibitor such as moclobemide is contraindicated. The antibiotic linezolid is a reversible non-selective MAO-inhibitor and should not be given to patients treated with escitalopram. Co-administration with serotonergic medicinal products (e.g. opioids (such as buprenorphine and tramadol), sumatriptan and other triptans) may lead to serotonin syndrome. SSRIs can lower the seizure threshold. Caution is advised when concomitantly using other medicinal products capable of lowering the seizure threshold (e.g. antidepressants (tricyclics, SSRIs), neuroleptics (phenothiazines, thioxanthenes and butyrophenones), mefloquin, bupropion and tramadol). Concomitant use of SSRIs and herbal remedies containing St. John´s Wort (Hypericum perforatum) may result in an increased incidence of adverse reactions. Altered anti-coagulant effects may occur when escitalopram is combined with oral anticoagulants. **Clonazepam:** Enhanced effects on sedation, respiration and haemodynamics may occur when clonazepam is co-administered with any centrally acting depressants e.g. alcohol, and other anticonvulsant (antiepileptic) agents, anaesthetics, hypnotics, psychoactive drugs, and some analgesics as well as muscle relaxants. Known inhibitors of hepatic enzymes, e.g. cimetidine, have been shown to reduce the clearance of benzodiazepines and may potentiate their action.

ADVERSE REACTIONS: Delayed ejaculation, confusion, vomiting, memory impairment, drowsiness, tiredness, anorgasmia (decreased orgasm), low sexual desire, nausea, diarrhea, and uncoordinated body movements.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

IN/FELIZ S LITE/CLONOTRIL PLUS 5/10 mg and 0.25 mg/MAY 2026/03/ABPI

(Additional information is available on request)