

ZAFIMOVE

“To be sold by retail on the prescription of Neurologists/ Geriatricians only”.

Abbreviated Prescribing information for ZAFIMOVE (Safinamide Tablets)

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

PHARMACOLOGICAL PROPERTIES: Safinamide acts through both dopaminergic and non-dopaminergic mechanisms of action. Safinamide is a highly selective and reversible MAO-B inhibitor causing an increase in extracellular levels of dopamine in the striatum. Safinamide is associated with state-dependent inhibition of voltage-gated sodium (Na⁺) channels, and modulation of stimulated release of glutamate.

DOSAGE AND ADMINISTRATION: Treatment with safinamide should be started at 50 mg per day. This daily dose may be increased to 100 mg/day because of individual clinical need preferably in the morning by mouth with water. ZAFIMOV may be taken with or without food. Elderly: No change in dose is required for elderly patients. Experience of use of safinamide in patients over 75 years of age is limited. Paediatric population: The safety and efficacy of safinamide in children and adolescents under 18 years of age have not been established.

CONTRAINDICATION: Concomitant use of the other drugs in the monoamine oxidase inhibitors [MAO] or other drugs that are potent inhibitors of monoamine oxidase (e.g., linezolid). The combination may result in increased blood pressure, including hypertensive crisis, Concomitant use of Opioid drugs (e.g., tramadol, meperidine and its derivatives, methadone or propoxyphene); serotonin-norepinephrine reuptake inhibitors (SNRIs); tri- or tetra-cyclic or triazolopyridine antidepressants; cyclobenzaprine; methylphenidate, amphetamine, and their derivatives; St. John's wort. Concomitant use could result in life-threatening serotonin syndrome, Concomitant use of Dextromethorphan. The combination of MAO inhibitors and dextromethorphan has been reported to cause episodes of psychosis or abnormal behaviour 1) A history of a hypersensitivity to safinamide 2) Severe hepatic impairment (Child-Pugh), Hypersensitivity to the active substance or to any of the excipients, Concomitant treatment with pethidine, Use in patients with albinism, retinal degeneration, uveitis, inherited retinopathy or severe progressive diabetic retinopathy.

WARNINGS & PRECAUTIONS: May cause or exacerbate hypertension, May cause serotonin syndrome when used with MAO inhibitors, antidepressants, or opioid drugs, May cause falling asleep during activities of daily living, May cause or exacerbate dyskinesia; consider levodopa dose reduction, May cause hallucinations and psychotic behaviour, May cause problems with impulse control/compulsive behaviors, May cause withdrawal-emergent hyperpyrexia and confusion

DRUG INTERACTION: Pharmacodynamic interactions: MAO inhibitors, pethidine, dextromethorphan, and antidepressants. Pharmacokinetic interactions: BCRP substrates (e.g., rosuvastatin, pitavastatin, pravastatin, ciprofloxacin, methotrexate, topotecan, diclofenac or glyburide) and OCT1 substrates.

ADVERSE REACTIONS: Insomnia, Urinary tract infection, Basal cell carcinoma, metabolism and nutrition disorders, anaemia, leukopenia, psychotic disorder, vertigo, cognitive disorder, tachycardia, orthostatic hypotension dyspnoea, gait disturbance, foot fracture, erectile dysfunction, dysuria, ankylosing spondylitis, hyperhidrosis, and Cataract.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

IN/ ZAFIMOVE 50, 100 mg/Jan-22/02/ABPI

(Additional information is available on request)