LASMIRAY

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

Abbreviated Prescribing information for **LASMIRAY**

(Lasmiditan Tablets 50 mg and 100 mg) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action:

Lasmiditan is a high affinity, centrally-penetrant, 5-hydroxytriptamine 1F (5-HT1F) receptor agonist. The precise mechanism of action is unknown, however, the therapeutic effects of lasmiditan in the treatment of migraine presumably involve agonistic effects at the 5-HT1F receptor, a decrease of neuropeptide release and an inhibition of pain pathways, including the trigeminal nerve.

INDICATIONS: It is indicated for the acute treatment of migraine with or without aura in adult.

DOSAGE AND ADMINISTRATION: The recommended dose is 1 tablet, to be given once daily depending upon severity of Pain or as directed by the Physician. Do not exceed Stated dose.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. Polyvinyl alcohol Titanium dioxide, Macrogol, Talc Iron oxide black, Iron oxide red.

WARNINGS & PRECAUTIONS:

Central nervous system (CNS) effects and driving impairment: Lasmiditan is associated with CNS adverse reactions. In a simulated driving study in healthy subjects, lasmiditan significantly impaired the ability to drive (see section 4.7). Patients should be advised not to drive or engage in other activities requiring heightened attention until at least 8 hours after taking each dose of lasmiditan. *Serotonin Syndrome:* Serotonin syndrome has been reported and may occur with lasmiditan or when administered with other serotonergic medicinal products [e.g, selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), and monoamine oxidase (MAO) inhibitors].

DRUG INTERACTIONS: *Heart rate lowering medicinal products:* Lasmiditan has been associated with a lowering of heart rate (HR). Propranolol and lasmiditan together decreased HR by a mean maximum of 19.3 bpm. This should be taken into consideration for patients in whom these magnitudes of HR decrease may pose a concern, including patients taking medicinal products that lower heart rate. *Serotonergic medicinal products:* Concomitant administration of lasmiditan and medicinal products (e.g., SSRIs, SNRIs, TCAs) that increase serotonin may increase the risk of serotonin syndrome. The risks of developing serotonin syndrome may be additive. Caution is advised. *Potential for lasmiditan to affect other medicinal products:* Following a single dose of lasmiditan, creatinine renal clearance over 24 hours decreased slightly (11 %) compared with placebo, without changes in GFR. *Potential for other medicinal products to affect lasmiditan:* No change in lasmiditan PK was observed when coadministered with sumatriptan or propranolol. Based on its metabolism clearance pathways, CYP inhibitors or inducers are unlikely to affect lasmiditan exposure and no change in lasmiditan PK was observed when coadministered with topiramate (CYP3A4 inducer and CYP2C19 inhibitor).-vitro.

ADVERSE REACTIONS: Hypersensitivity, Sleep abnormalities, Confusion Hallucinations, euphoric mood, Anxiety, Restlessness, Incoordination, Paraesthesia, Hypoaesthesia, Somnolence, Lethargy, Disturbance in attention, Cognitive disorder, Mental impairment, Tremor, Speech abnormalities, Serotonin syndrome, Visual impairment, Vertigo, Palpitations, Dyspnoea, Vomiting Nausea, Muscular

weakness, Muscle spasm, Limb discomfort, Feeling abnormal, Fatigue, Malaise, Chest discomfort, Feeling hot or feeling cold, Dizziness.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

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(Additional information is available on request)