SILOXIO M 25 & SILOXIO M 50

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

Abbreviated Prescribing information for SILOXIO M 25 & SILOXIO M 50 [Silodosin 8 mg/8 mg and Mirabegron (ER) 25 mg/50 mg Tablets]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: ***Mirabegron-*** It relaxes the detrusor smooth muscle during the storage phase of the urinary bladder fill-void cycle by activation of beta-3 AR which increases bladder capacity. ***Silodosin-*** Silodosin is a selective antagonist of post-synaptic alpha-1 adrenoreceptors, which are located in the human prostate, bladder base, bladder neck, prostatic Tablets, and prostatic urethra. Blockade of these alpha-1 adrenoreceptors can cause smooth muscle in these tissues to relax, resulting in an improvement in urine flow and a reduction in BPH symptoms.

INDICATIONS: It is indicated for an adult patients diagnosed with benign prostatic hyperplasia complicated by overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency.

DOSAGE AND ADMINISTRATION: ***Mirabegron-*** The recommended starting dosage of Mirabegron is 25 mg orally once daily. If needed, increase to the maximum dosage of Mirabegron 50 mg orally once daily after 4 to 8 weeks. Administration instructions for Mirabegron differ based on the patient population. Adult patients: Swallow Mirabegron whole with water. Do not chew, divide, or crush. Take with or without food. ***Silodosin-*** The recommended dose is 8 mg orally once daily with a meal.

CONTRAINDICATION: ***Mirabegron-*** It is contraindicated in patients with known hypersensitivity reactions to mirabegron or any inactive ingredients of the tablet. ***Silodosin-*** It is contraindicated in ***s***evere renal impairment (CCr < 30 mL/min), severe hepatic impairment (Child-Pugh score $\geq$ 10), concomitant administration with strong Cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ketoconazole, clarithromycin, itraconazole, ritonavir) and in patients with a history of hypersensitivity to silodosin or any of the ingredients of Silodosin.

WARNINGS & PRECAUTIONS: ***Mirabegron-*** Periodic blood pressure determinations are recommended, especially in hypertensive patients. Mirabegron is not recommended for use in patients with severe uncontrolled hypertension. In patients taking Mirabegron, urinary retention has been reported to occur in patients with bladder outlet obstruction (BOO) and in patients taking muscarinic antagonist medications for the treatment of OAB. Angioedema of the face, lips, tongue, and/or larynx has been reported with Mirabegron. ***Silodosin-*** Postural hypotension, with or without symptoms (e.g., dizziness) may develop when beginning Silodosin treatment. Patients should be cautioned about driving, operating machinery, or performing hazardous tasks when initiating therapy. The dose of Silodosin should be reduced to 4 mg in patients with moderate renal impairment. Silodosin is contraindicated in patients with severe renal impairment. Intraoperative Floppy Iris Syndrome has been observed during cataract surgery in some patients on alpha-1 blockers or previously treated with alpha-1 blockers. Concomitant use of Alpha-adrenergic blockers and PDE5 inhibitors can potentially cause symptomatic hypotension.

DRUG INTERACTIONS: ***Mirabegron-*** Since Mirabegron is a moderate CYP2D6 inhibitor, the systemic exposure to CYP2D6 substrates is increased when co-administered with Mirabegron. Therefore, appropriate monitoring and dose adjustment may be necessary, especially with narrow therapeutic index drugs metabolized by CYP2D6. For patients who are initiating a combination of mirabegron and digoxin, the lowest dose for digoxin should initially be considered. ***Silodosin-***

Concomitant administration with moderate CYP3A4 inhibitors (e.g., diltiazem, erythromycin, verapamil) may increase concentration of Silodosin. Exercise caution and monitor patients for adverse events when co-administering Silodosin with moderate CYP3A4 inhibitors.

ADVERSE REACTIONS: ***Mirabegron*****-** Hypertension, urinary retention, angioedema of the face, lips, tongue, and larynx, with or without respiratory symptoms, nausea, diarrhea, constipation, dizziness, tachycardia, headache, nasopharyngitis, urinary tract infection, upper respiratory tract infection, arthralgia, abdominal pain, fatigue, palpitations, glaucoma, dyspepsia, gastritis, abdominal distension, sinusitis, rhinitis, GGT increased, AST increased, ALT increased, LDH increased, bilirubin increased, nephrolithiasis, bladder pain, vulvovaginal pruritus, vaginal infection, urticaria, leukocytoclastic vasculitis, rash, pruritus, purpura, lip edema, back pain, influenza, cystitis, stevens-johnson syndrome, atrial fibrillation, confusion, hallucinations, insomnia, and anxiety. ***Silodosin*****-** Retrograde ejaculation, dizziness, diarrhea, orthostatic hypotension, headache, nasopharyngitis, nasal congestion, insomnia, PSA increased, sinusitis, abdominal pain, asthenia, rhinorrhea, toxic skin eruption, purpura, skin rash, pruritus, urticaria, jaundice, impaired hepatic function associated with increased transaminase values, swollen tongue, and pharyngeal edema.

MARKETED BY:

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Torrent Pharmaceuticals Limited.

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(Additional information is available on request)