MIDORISE

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

Abbreviated Prescribing information for MIDORISE [Midodrine Hydrochloride Tablets U.S.P.]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Midodrine hydrochloride is the rapidly absorbed pro-drug of the pharmacologically active constituent desglymidodrine. Desglymidodrine is a sympathomimetic agent with a direct and selective effect on the peripheral α 1-adrenergic receptors.

INDICATIONS: It is indicated for the treatment of symptomatic orthostatic hypotension.

DOSAGE AND ADMINISTRATION: 2.5 mg three times a day (Midodrine hydrochloride 2.5 mg tablets are also available). Depending on the results of supine and standing blood pressure recordings, this dose may be increased weekly up to a dose of 10 mg three times a day. This is the usual maintenance dosage. Midodrine hydrochloride 10 mg tablets may be taken with food. For oral use.

CONTRAINDICATION: Severe organic heart disease (e.g. bradycardia, heart attack, congestive heart failure, cardiac conduction disturbances or aortic aneurysm), Hypertension, Serious obliterative blood vessel disease, cerebrovascular occlusions and vessel spasms, Acute kidney disease, Severe renal impairment (creatinine clearance of less than 30 ml/min), Serious prostate disorder, Urinary retention, Proliferative diabetic retinopathy, Pheochromocytoma, Hyperthyroidism, Narrow angle glaucoma, Hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS: Regular monitoring of supine and standing blood pressure is necessary due to the risk of hypertension in the supine position, e.g. at night. If supine hypertension occurs, which is not overcome by reducing the dose, treatment with midodrine hydrochloride must be stopped. In patients suffering from a severe disturbance of the autonomic nervous system, administration of midodrine hydrochloride may lead to a further reduction of blood pressure when standing. Caution must be observed in patients with atherosclerotic disease especially with symptoms of intestinal angina or claudication of the legs. Caution is advised in patients with prostate disorders. Use of the drug may cause urinary retention. This medicinal product is contraindicated in patients with acute renal impairment or severe renal impairment. Slowing of the heart rate may occur after midodrine hydrochloride administration, due to vagal reflex. Caution is advised when midodrine hydrochloride is used concomitantly with cardiac glycosides (such as digitalis preparations) and other agents that directly or indirectly reduce heart rate. Patients should be monitored for signs or symptoms suggesting bradycardia.

DRUG INTERACTIONS: Concomitant treatment with sympathomimetics and other vasoconstrictive substances such as reserpine, guanethidine, tricyclic antidepressants, antihistamines, thyroid hormones and MAO-inhibitors, including treatments that are available without prescription, should be avoided as a pronounced increase in blood pressure may occur. As with other specific α-adrenergic agonists, the effect of midodrine hydrochloride is blocked by α-adrenergic antagonists such as prazosin and phentolamine. Monitoring is recommended if midodrine hydrochloride is combined with other drugs that directly or indirectly reduce the heart rate. Simultaneous use of digitalis preparations is not recommended, as the heart rate reducing effect may be potentiated by midodrine hydrochloride and heart block may occur. Midodrine hydrochloride may potentiate or enhance the hypertensive effects of corticosteroid preparations. Midodrine is an inhibitor of CYP2D6 and may affect the metabolism of other drugs. Patients taking midodrine may have falsely elevated plasma metanephrine as a result of analytical interference when measured by HILIC-based HPLC-MS/MS.

ADVERSE REACTIONS: Sleep disorders, insomnia, anxiety, confusional state, paraesthesia,

paraesthesia of the scalp, headache, restlessness, excitability, irritability, reflex bradycardia, tachycardia, palpitations, supine hypertension (dose dependent effect), nausea, dyspepsia, stomatitis, abdominal pain, vomiting, diarrhoea, abnormal hepatic function, raised liver enzymes, piloerection (goose bumps), pruritus of the scalp, pruritus, chills, flushing, rash, dysuria, urinary retention, urinary urgency.

MARKETED BY:

Torrent Pharmaceuticals Limited.

IN/MIDORISE 2.5, 5, and 10 mg/MAY 2026/02/ABPI

(Additional information is available on request)