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: The alpha sympathomimetic drug midodrine hydrochloride is a prodrug, which is converted to its pharmacologically active metabolite desglymidodrine in various tissues.

INDICATION: Midodrine is indicated in the treatment of symptomatic orthostatic hypotension.

DOSAGE AND ADMINISTRATION: Dose must be taken as directed by Physician**.** The usual initial dosage is 2.5 mg of midodrine hydrochloride 2-3 times daily. The maximum daily dosage is 30 mg midodrine hydrochloride, divided into 3 single doses and this limit can be exceeded only in exceptional cases. Midodrine 5 mg tablets should be taken during daytime when the patient performs his daily activities in upright position.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients, Hypertension, Severe organic heart disease or congestive heart failure, Thyrotoxicosis, Pheochromocytoma, Acute nephritis, Acute renal disease, Severe renal insufficiency (creatinine clearance <30 ml/min), Hypertrophy of the prostate gland with residual urine volume increased, Proliferative diabetic retinopathy, Urinary retention, Hyperthyroidism, Narrow angle glaucoma, Obliterative or spastic vessel disease (e.g. cerebrovascular occlusions and spasms) and Vasovagal hypotension.

WARNINGS & PRECAUTIONS: Regular monitoring of blood pressure in supine and sitting position is required. The patients should be informed to report any symptoms of supine hypertension such as palpitations, headaches, blurred vision to the attending physician and the patient should be advised to discontinue the medication immediately. The dosage should be adjusted in this case or treatment with midodrine hydrochloride should be terminated. Patients taking midodrine should avoid concomitant use of other adreno-sympathomimetic drugs including over the counter remedies. Slowing of the heart rate may occur after administration of midodrine, primarily due to vagal reflex, therefore great caution should be taken when using it together with other agents that directly or indirectly slow the heart rate e.g. digitalis, beta blockers, psychopharmacologic agents (specifically tricyclic antidepressants, phenothiazines and atypical antipsychotics). Patients experiencing any signs or symptoms suggestive of bradycardia (pulse slowing, increased dizziness, syncope, cardiac awareness) should be advised to discontinue midodrine. The use of midodrine in patients who have an increased risk of or suffer from glaucoma / increased intra-ocular pressure or who are treated with mineralocorticoids / fludrocortisone acetate (which may increase intra-ocular pressure) should be avoided or monitored very closely. It is advisable to monitor the renal function and blood pressure in case of long-term treatment with midodrine tablets. Monitoring the liver function before and during treatment with midodrine tablets.

DRUG INTERACTIONS: Midodrine hydrochloride is a cytochrome P450 CYP2D6 inhibitor and can therefore influence the metabolism of other medicines (eg., Perphenazine, Amiodarone, Metoclopramide), which are metabolized through this cytochrome 450 isoenzyme. This may lead to increased systemic exposure and increased effects of this medicinal product. *Tricyclic antidepressants, alpha-sympathomimetic medicines, thyroid hormones, antihistamines, MAO inhibitor:* Enhanced sympathomimetic activity (undesired high blood pressure increase). Simultaneous usage is not recommended. *Alpha and beta receptor blockers:* The effect of increased blood pressure of Midodrine hydrochloride can be antagonised by alpha receptor blocker. *Cardiac glycosides:* The reflex bradycardia of midodrine hydrochloride may be increased by bradycardiac effect of glycosides. *Corticosteroid preparations:* Patients being treated with

midodrine in combination with, mineralocorticoids or glucocorticoids may be at increased risk of glaucoma/increased intraocular pressure, and should be carefully monitored.

ADVERSE REACTIONS:

Very common: may affect more than 1 in 10 people: goose bumps, difficulty/pain in urination. *Common: may affect up to 1 in 10 people*: discomfort of skin, e.g. tingling (paraesthesia), rash, itching of the scalp, chills, flushing, high blood pressure in supine position (blood pressure ≥ 180 to 110 mmHg) with daily maximum dosage of more than 30 mg per day (this might cause headaches, blurred vision, a 'pounding' heartbeat, chest pain or shortness of breath), nausea, vomiting, indigestion, inflammation of mucous membrane, inability to pass urine. *Uncommon: may affect up to 1 in 100 people*: insomnia and problems in sleeping, headaches, restlessness, irritability, excitability, reflex slowing of pulse, palpitation, cardiac rhythm disorders, increased pulse frequency, high blood pressure in supine position (blood pressure ≥ 180 to 110 mmHg) with daily maximum dosage of up to 7.5 mg, stomach pain, sudden urge to urinate. *Rare: may affect up to 1 in 1000 people:* dizziness or lightheadedness, visual disturbances, chest pain, stroke, liver function disorders, increased liver enzymes. *Not known (frequency cannot be estimated from the available data):* anxiety, confusion, increased tear production, diarrhoea.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

IN/MIDORISE 2.5, 5 and 10 mg/ MAR-22/01/ABPI
(Additional information is available on request)