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

MIDORISE

1. GENERIC NAME

Midodrine Hydrochloride Tablets U.S.P.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

MIDORISE 2.5

Each uncoated tablet contains:

Midodrine Hydrochloride U.S.P. ……..2.5 mg

Excipients ……..q.s

The excipients used are Microcrystalline Cellulose, Corn Starch, Croscarmellose Sodium, Colloidal Silicon Dioxide and Magnesium Stearate.

MIDORISE 5

Each uncoated tablet contains:

Midodrine Hydrochloride U.S.P. ……..5 mg

Excipients ……..q.s

The excipients used are Microcrystalline Cellulose, Corn Starch, Croscarmellose Sodium, Colloidal Silicon Dioxide and Magnesium Stearate.

MIDORISE 10

Each uncoated tablet contains:

Midodrine Hydrochloride U.S.P. ……..10 mg

Excipients ……..q.s

The excipients used are Microcrystalline Cellulose, Corn Starch, Croscarmellose Sodium, Colloidal Silicon Dioxide and Magnesium Stearate.

3. DOSAGE FORM AND STRENGTH

Uncoated tablet, 2.5/5/10 mg strength.

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

It is indicated for the treatment of symptomatic orthostatic hypotension.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

The usual initial dosage is 2.5 mg of midodrine hydrochloride 2-3 times daily. The dose should be increased at weekly intervals in small increments until an optimal response is obtained. The maintenance dosage should be determined individually for each patient to achieve optimal therapeutic effect while reducing the impact of adverse reactions.

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. A dosing schedule of 3-4 hour intervals is suggested. The last dose should be taken at least four hours before bedtime to reduce the risk of supine hypertension. Blood pressure in supine and sitting position should be regularly monitored at the beginning of the treatment (at least twice a week). Treatment with Midodrine 2.5 mg tablets should be stopped if supine hypertension is significantly excessive.

Midodrine 5 mg tablets should be taken with sufficient amount of fluid. They can be taken during meal time. The duration of treatment is based on the progression of the disease**.**

4.3 CONTRAINDICATIONS

Contraindicated in the following situations:

- 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)
- Vasovagal hypotension

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Regular monitoring of blood pressure in supine and sitting position is required during treatment with midodrine tablets. Patients with diabetes mellitus who show high blood pressure levels in supine position due to underlying neurological disorders (diabetic autonomic neuropathy) may suffer from supine hypertension with midodrine tablets. Hence, special caution is recommended.

Any possible danger to the patients should be ruled out before starting treatment with midodrine tablets. 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. Supine hypertension may also be controlled by elevation of the head.

The treatment should not be continued in patients suffering from severely fluctuating blood pressure with midodrine tablets.

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. Sufficient data is not available for patients with hepatic impairment. Therefore, it is advisable to monitor the liver function before and during treatment with midodrine tablets.

4.5 DRUG INTERACTION

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 (e.g. Prazosin or Phentolamine). The cardiac frequency reducing effect of beta blockers can be potentiated by midodrine hydrochloride. The concomitant use of alpha- and beta-receptor blocking agents (which reduce the heart rate and midodrine requires careful monitoring.

Cardiac glycosides	The reflex bradycardia of midodrine hydrochloride may be increased by bradycardiac effect of glycosides. Therefore, simultaneous usage is not recommended.
Ergot alkaloid	Deterioration of peripheral blood circulation. The patient may experience an increase in blood pressure and reduced blood flow to organs and hands/feet. Avoid concomitant use of drugs that increase blood pressure. If concomitant use cannot be avoided, the blood pressure is to be monitored closely.
Corticosteroid preparations	Patients being treated with midodrine in combination with, mineralocorticoids or glucocorticoids (e.g. fludrocortisone) may be at increased risk of glaucoma/increased intraocular pressure, and should be carefully monitored. Midodrine may enhance or potentiate the possible hypertensive effect of corticosteroid preparations.

4.6 USE IN SPECIAL POPULATION

There are no reported data from the use of midodrine in pregnant women. The reported animal studies have shown reproductive toxicity.

Midodrine is not recommended during pregnancy and in women of childbearing potential not using contraception. Any woman becoming pregnant during treatment should be withdrawn from the treatment immediately upon established pregnancy.

Breast-feeding

It is unknown whether midodrine/metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. Midodrine should not be used during breast-feeding.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Patients who experience dizziness or light headedness while receiving Midodrine should refrain from operating machinery.

4.8 UNDESIRABLE EFFECTS

The following frequency categories are used for the evaluation of side-effects:

Very common (≥ 1/10)

Common (≥ 1/100 to < 1/10)

Uncommon (≥ 1/1000 to < 1/100)

Rare (≥ 1/10000 to < 1/1000)

Very rare (< 1/10000)

Not known frequency cannot be estimated based on the available data

System organ class	Very common	Common	Uncommon	Rare	Very rare	Unknown
Psychiatric disorders			Sleep disorders, insomnia			Anxiety, confusional state
Nervous system disorders		Paraesthesia	Headaches, restlessness, excitability, irritation	Dizziness or light headedness		
Eye disorders				Visual disturbance		Increased tear production
Cardiac disorders			Reflex bradycardia, palpitations, ventricular arrhythmia, tachycardia	Chest pain		
Vascular disorders		Supine hypertension (blood pressure ≥ 180/110 mmHg) with daily doses of	Supine hypertension (blood pressure ≥ 180/110 mmHg) with daily	Cerebrovascular accident		

		more than 30 mg	doses up to 7.5 mg			
Gastrointestinal disorders		Nausea, vomiting, stomatitis dyspepsia	Abdominal pain			Diarrhoea
Hepatobiliary disorders				Hepatic function abnormal, increased liver enzyme		
Skin and subcutaneous tissue disorders	Piloerection (goose bumps),	Chills, skin rash, pruritus (mainly of the scalp), flushing				
Renal and urinary disorders	Dysuria	Urinary retention	Urinary urgency			

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: https://www.torrentpharma.com/index.php/site/info/adverse_event_reporting

4.9 OVERDOSE

Overdosage of midodrine produces piloerection, sensation of coldness, an urgent desire to empty the bladder, hypertension and bradycardia.

These effects can be counteracted by induced emesis and administration of alpha-sympatholytic drugs. In marked bradycardia, atropine may be given at its usual dose. In exanthema, H-1 antihistamines should be administered.

The active metabolite desglymidodrine is dialysable.

5. PHARMACOLOGICAL PROPERTIES

5.1 MECHANISM OF ACTION

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

5.2 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Cardiac stimulants, excluding cardiac glycoside.

ATC-Code: C01CA17

Desglymidodrine is a selective alpha-1-adrenoreceptor agonist. Its effect on cardiac circulation system is mainly due to increase of systolic and diastolic blood pressure. This increase in blood pressure occurs due to arterial and venous vasoconstriction. Midodrine hydrochloride triggers alpha receptors at the bladder, which in turn is connected with increase of tone at bladder exit and delayed emptying of the bladder.

5.3 PHARMACOKINETIC PROPERTIES

Absorption

After oral administration of a dose of 2.5 mg, midodrine hydrochloride is rapidly and completely absorbed and reaches its peak plasma concentrations after approximately 20-30 minutes (Cmax approx. 0.01 mg/l, tmax < 30 min). The prodrug midodrine hydrochloride is converted in different tissues (also in liver) enzymatically into its active metabolite desglymidodrine. The absolute bioavailability of midodrine hydrochloride (and desglymidodrine) amounts to 93% after oral administration.

AUC and Cmax increase proportionally to the doses in a dosage range of 2.5 – 22.5 mg. Administration with food increases the AUC by approximately 25%, and the Cmax decreases by approximately 30%. The pharmacokinetics of desglymidodrine is not affected.

After oral administration of a dosage of 5 – 10 mg of midodrine hydrochloride in fasting patients with orthostatic hypertension, desglymidodrine reaches its highest plasma concentration (0.027 mg/l) approx. 1h after oral administration (tmax = 1.1 h) and after intravenous injection within a period of 60 – 120 min.

Distribution

The distribution of midodrine in humans was not analysed.

Midodrine and desglymidodrine bind less than 30% to plasma proteins. In reported studies on animals show that desglymidodrine is distributed in the target organs. The distribution of midodrine in humans has not been established, it does not appear to cross the blood-brain barrier after oral administration.

Biotransformation

This medicinal product is split into its pharmacologically active metabolite desglymidodrine through enzymatic degradation in different tissues (including liver).

Elimination

Midodrine hydrochloride is quickly eliminated from plasma ($t_{1/2}$ = 0.41 – 0.49 h), and desglymidodrine is eliminated somewhat slowly ($t_{1/2}$ = 3 h).

Midodrine hydrochloride and desglymidodrine are almost completely (91%) eliminated renally within 24 hours (approx. 40 – 60% as active metabolite, 2 – 5% as non-metabolised midodrine hydrochloride, the rest as other pharmacologically inactive metabolites). The elimination of midodrine hydrochloride or desglymidodrine through faeces is negligible.

After intravenous administration, 53% of applied quantity was eliminated in the first 4 hours and 47% through urine after per oral administration. The faecal elimination is 2.1%.

Special populations

To date there are no pharmacological data about midodrine or its metabolites desglymidodrine in older patients or patients with renal and/or liver function disorders.

6. NON-CLINICAL PROPERTIES

6.1 ANIMAL TOXICOLOGY OR PHARMACOLOGY

Reported non-clinical data revealed no special hazard for humans based on conventional studies of safety pharmacology and repeated dose toxicity.

Reproduction toxicity

Reported studies in rats and rabbits have shown embryo toxicity, but no teratogenic effects are reported.

Genotoxicity

In-vitro and in-vivo reported studies for midodrine hydrochloride did not show any indication of mutagenic or genotoxic potential.

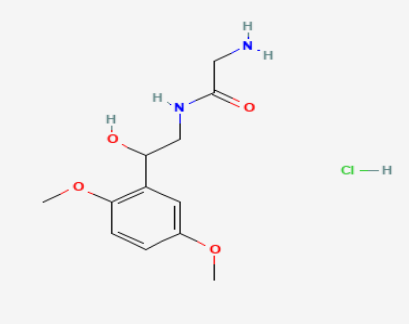
Carcinogenicity

Increased tumour incidence in the testicular interstitial cells was observed in reported carcinogenicity studies. The relevance of this observation for humans is not clear.

7. DESCRIPTION

MIDODRINE HYDROCHLORIDE

Midodrine Hydrochloride is 2-amino-N-[2-(2,5-dimethoxyphenyl)-2-hydroxyethyl] acetamide; hydrochloride. The empirical formula is $C_{12}H_{19}ClN_2O_4$ and its molecular weight is 290.74. Its structural formula is:



Midodrine Hydrochloride Tablets are white colour, round shaped, uncoated tablet, plain on both sides. The excipients used are Microcrystalline Cellulose, Corn Starch, Croscarmellose Sodium, Colloidal Silicon Dioxide and Magnesium Stearate.

8. PHARMACEUTICAL PARTICULARS

8.1 Incompatibilities

Not available

8.2 Shelf Life

Do not use later than date of expiry

8.3 Packaging Information

MIDORISE 2.5 is available in Blister pack of 20 tablets.

MIDORISE 5 & 10 is available in Blister pack of 10 tablets

8.4 Storage and handling instructions

STORE BELOW 25˚C.

9. PATIENT COUNSELLING INFORMATION

Package leaflet: Information for the user

MIDORISE

Midodrine Hydrochloride Tablets U.S.P.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet. You may need to read it again.

• If you have any further questions, ask your doctor or pharmacist.

• **This medicine has been prescribed for you only.** Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

• If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

9.1. What MIDORISE is and what it is used for

MIDORISE contain the active ingredient midodrine hydrochloride.

MIDORISE is used for the treatment of symptomatic orthostatic hypotension.

9.2. What you need to know before you take MIDORISE

Do not take MIDORISE if

- if you are allergic to midodrine hydrochloride or any of the other ingredients of this medicine;

- if you are suffering from high blood pressure or a form of low blood pressure known as vasovagal hypotension;

- if you have tumour near the kidney, known as phaeochromocytoma;

- if you have narrowing vascular disorders;

- if you have elevated eye pressure (glaucoma);

- if you have a slow pulse;

- if you are finding it difficult to urinate, especially due to enlargement of the prostate gland

- if you have damage to the retina in your eye as a result of diabetes (known as proliferative diabetic retinopathy)

- if you have an overactive thyroid gland;

- if your blood pressure and heart beat rate in standing test increases due to circulatory disorders with lower blood pressure;

- if you have some forms of heart or blood vessel disease;

- if you have inflammation of the kidneys, kidney disease, poor kidney function or if you are having problems passing urine.

If you do not currently suffer from the listed diseases, but you did suffer from any of them in the past, talk to your doctor or pharmacist before taking Midodrine.

Do not take **MIDORISE** if any of the above applies to you. If you are not sure, talk to your doctor before taking **MIDORISE**

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Midodrine if you have:

• been told you have high blood pressure when you lie down

• high blood sugar (diabetes mellitus)

Your blood pressure will be monitored before starting, and during, treatment. Regular monitoring of your blood pressure when you are lying down and when you are standing up will be required as there may be a risk of your blood pressure rising when you lie down, for example, at night. If your blood pressure does go up when you lie down, reducing the dose does not correct the problem, treatment with this medicine must be stopped.

You should take your last dose of Midodrine at least four hours before bedtime. This is because Midodrine can cause high blood pressure if you are lying down for any period of time (for example, sleeping or sunbathing).

You should have your blood pressure, kidney and liver function checked by your doctor before you start using this medicine. During treatment with this medicine, your blood pressure will be checked regularly.

If you experience palpitations, headaches, blurred vision, especially before going to sleep, stop taking the product and seek medical help immediately. Your doctor will then decide whether to adjust your dose or stop your treatment with Midodrine completely.

You should not continue with the treatment if you have severe fluctuations of blood pressure when you are undergoing treatment with Midodrine.

When you are undergoing treatment with Midodrine, talk to your doctor or pharmacist before taking any new prescribed drugs and other over the counter drugs (see also "Taking Midodrine with other medicinal products").

Talk to your doctor or pharmacist if you know you are at increased risk of eye problems such as glaucoma**.**

Children and adolescents

Do not give this medicine to children and adolescents under the age of 18 because the safety and efficacy of midodrine hydrochloride tablets in patients aged below 18 years has not been established.

Elderly patients (older than 60 years)

The initial dosage is small and the increase in dose is dependent on the patient's clinical condition and should be done with caution.

Patients with renal function disorders

Due to lack of data, information regarding dosage adjustment cannot be provided for patients with renal function disorders. In general, Midodrine should not be administered in patients with acute renal disorders and severe renal function disorders.

Patient with hepatic impairment

Since sufficient experience in patients with hepatic impairments is not available, the liver function should be regularly monitored before and during treatment with Midodrine.

Taking Midodrine with other medicinal products

Please inform your doctor or pharmacist if you take other medicinal products, have taken other medicines a while ago or intend to take other medicinal products, including medicines obtained without a prescriprion.

The active ingredient midodrine hydrochloride can influence the way some medicines work and may strengthen their effectiveness.

Midodrine hydrochloride may increase the effect of Amiodarone (used to control heart arrhythmias) and metoclopramide (used to stop you feeling and being sick). Midodrine hydrochloride may also increase the effect of this drug phenothiazines and atypical antipsychotics for schizophrenia or psychosis.

Taking certain medicines, which belong to the class of tricyclic antidepressants (medicines to treat depression), medicines for blood pressure stabilisation, thyroid hormones, anti-histamines (medicines to treat allergies), MAO inhibitors (medicines to treat depression) and corticosteroids (medicines to treat asthma, skin eczema, autoimmune disorders), may enhance the blood pressure increasing effect of midodrine hydrochloride. It may result in an undesirable increase in blood pressure. Therefore, combination with Midodrine is not recommended.

Alpha- and beta-receptor blockers (medicines which reduce blood pressure) can weaken the blood pressure-increasing effect of Midodrine. The cardiac frequency reducing effect of medicinal products, which are called beta blockers, can be enhanced. Careful monitoring by the doctor is required.

If you are taking glycosides to increase the force of your heart beat e.g. digitalis, combination of these products with <Prodcut name> is not recommended.

The combination of midodrine hydrochloride with medicines used against migraines and Parkinson, called Ergot alkaloid are to be avoided due to increase in blood pressure. If concomitant use cannot be avoided, the blood pressure is to be monitored closely.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you get pregnant during treatment with Midodrine, you must stop the treatment immediately once pregnancy is confirmed.

Midodrine is not recommended during pregnancy.

The administration of Midodrine is not recommended during breastfeeding

9.3. How to take MIDORISE.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The tablet can be divided into equal doses.

Midodrine 2.5 mg

The usual initial dosage is 2.5 mg (1 tablet) 2 to 3 times daily orally. Your doctor may increase this dose each week until the best effect is seen..

The maximum daily dosage is 30 mgand this limit should be exceeded only in exceptional cases.

Midodrine 5 mg

The usual initial dosage is 2.5 mg 2 to 3 times daily orally. Your doctor may increase this dose each week until the best effect is seen.

The maximum daily dosage is 30 mg and this limit should be exceeded only in exceptional cases.

Timing of the evening dose

Please take Midodrine with a glass of water. Midodrine can be taken with meals. You should take your last dose of Midodrine at least four hours before bedtime. This is because Midodrine can cause high blood pressure if you are lying down for any period of time (for example, sleeping or sunbathing).

Use in children and adolescents

Do not give this medicine to children and adolescents under the age of 18 because the safety and efficacy of midodrine hydrochloride tablets in patients aged below 18 years has not been established.

Use in elderly patients

The initial dosage is small and the increase in dose is dependent on the patient’s clinical condition and should be done with caution.

Patients with renal function disorders

Due to lack of data, information regarding dosage adjustment cannot be provided for patients with renal function disorders. In general, Midodrine should not be administered in patients with acute renal disorders and severe renal function disorders.

Patients with hepatic impairment

No specific reported studies have been performed in this patient population for dosage adjustment. Therefore, information regarding dosage adjustment is not available for this group.

Duration of use

The duration is based on the progression of the disease.

Please talk to your doctor if you have the feeling that the effect of Midodrine is strong or weak.

If you take more MIDORISE

If you take more Midodrine, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this package leaflet to your doctor.

Overdose may result in very high blood pressure, feeling of cold, urination difficulties as well as prolongation of pulse and "goose bumps", especially in the neck and scalp area.

Depending on the severity of overdose, the doctor may initiate measures such as induced vomiting and administration of an antidote (alpha receptor blocker such as Phentolamine, Nitroprusside or Nitroglycerin).

A slowing down of pulse can be rectified with Atropine. Treatment with dialysis is a further possibility.

If you forget to take MIDORISE

If you forget to take a dose, take your next dose at the usual time and then keep taking your medicine as told by your doctor. Do not take a double dose to make up for a forgotten dose.

If you stop taking MIDORISE

If you stop taking your medicine, there should not be a sudden drop in your blood pressure, however it is important that you discuss with your doctor before you consider stopping this medicine.

Please contact your doctor or pharmacist if you have any questions regarding the use of this medicinal product.

9.4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You may suffer from any of the following side effects:

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

https://www.torrentpharma.com/index.php/site/info/adverse_event_reporting

9.5. How to store MIDORISE

STORE BELOW 25˚C.

9.6 Contents of the pack and other information

MIDORISE 2.5

The active substances in MIDORISE is Midodrine Hydrochloride 2.5 mg

The excipients used are Microcrystalline Cellulose, Corn Starch, Croscarmellose Sodium, Colloidal Silicon Dioxide and Magnesium Stearate.

MIDORISE 2.5 is available in Blister pack of 20 tablets.

MIDORISE 5

The active substances in MIDORISE is Midodrine Hydrochloride 5 mg

The excipients used are Microcrystalline Cellulose, Corn Starch, Croscarmellose Sodium, Colloidal Silicon Dioxide and Magnesium Stearate.

MIDORISE 10

The active substances in MIDORISE is Midodrine Hydrochloride 10 mg

The excipients used are Microcrystalline Cellulose, Corn Starch, Croscarmellose Sodium, Colloidal Silicon Dioxide and Magnesium Stearate.

MIDORISE 5 & 10 is available in Blister pack of 10 tablets

10. DETAILS OF MANUFACTURER

Manufactured in India by:

BDR Pharmaceuticals Int'I Pvt. Ltd.

Vanseti Village, PO. Tajpura,Taluka : Halol, Dist : Panchmahal-389 350.

11. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE

Mfg. Lic. No.: G/25/2534 issued on 04.03.2022

12. DATE OF REVISION

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/ MIDORISE 2.5, 5, 10 mg/Mar-22/01/PI