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MIDORIN-10

Midodrine Hydrochloride Tablets USP 10 mg

Composition:

Each uncoated tablet contains:
Midodrine Hydrochloride USP... 10mg
Excipients q.s.
Approved colour used.

Pharmaceutical Form:

Uncoated Tablets

Therapeutic indications:

MIDORIN-10 is used in the treatment of hypotensive states and in particular of orthostatic hypotension. Alpha-agonist drugs such as midodrine have also been used as an adjunct in the management of urinary incontinence.

Posology and method of administration:

Posology:

For hypotensive states: Usual initial dose 2.5 mg two or three times daily, adjusted gradually according to response; up to 10 mg three times daily may be required.

The potential for supine hypertension is reduced by taking the last dose of the day at least 4 hours before bedtime.

For urinary incontinence: 2.5 to 5 mg two or three times daily.

Method of administration:

For oral use.

Contraindications:

- MIDORIN-10 are contraindicated for;
- 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 of the formulation.

Warnings and Precautions:

Severe orthostatic hypotension with supine hypertension:

Regular monitoring of supine and standing blood pressure is necessary due to the risk of hypertension in the supine position, e.g. at night. Patients should be told to report symptoms of supine hypertension immediately such as chest pain, palpitations, shortness of breath, headache and blurred

vision, and should be monitored for these side effects by the treating physician. Supine hypertension may often be controlled by an adjustment to the dose. If supine hypertension occurs, which is not overcome by reducing the dose, treatment with midodrine hydrochloride must be stopped.

Severe disturbances of the autonomic nervous system:

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. If this occurs, further treatment with midodrine hydrochloride should be stopped.

Atherosclerotic disease:

Caution must be observed in patients with atherosclerotic disease especially with symptoms of intestinal angina or claudication of the legs.

Prostate disorders:

Caution is advised in patients with prostate disorders. Use of the drug may cause urinary retention.

Renal and hepatic function:

This medicinal product is contraindicated in patients with acute renal impairment or severe renal impairment. Treatment with midodrine hydrochloride has not been studied in patients with hepatic impairment. It is therefore recommended to evaluate the renal and hepatic parameters before starting treatment with midodrine hydrochloride and on a regular basis.

Heart rate:

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:

Sympathomimetics and other vasopressor agents:

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.

Alpha-adrenergic antagonists:

As with other specific α -adrenergic agonists, the effect of midodrine hydrochloride is blocked by α -adrenergic antagonists such as prazosin and phentolamine.

Heart rate reducing drugs:

Monitoring is recommended if midodrine hydrochloride is combined with other drugs that directly or indirectly reduce the heart rate.

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Glycosides:

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.

Corticosteroid preparations:

Midodrine hydrochloride may potentiate or enhance the hypertensive effects of corticosteroid preparations. Patients being treated with midodrine hydrochloride in combination with mineralocorticoids or glucocorticoids (e.g. fludrocortisone) may be at increased risk of glaucoma/increased intraocular pressure, and should be carefully monitored.

Potential pharmacokinetic interactions

The potential for pharmacokinetic interaction is limited as the metabolic pathways do not involve cytochrome P450 enzymes. However, decreased clearance of medicinal products metabolised by CYP2D6 (e.g. promethazine) may occur.

Potential effect of other drugs on midodrine:

Concomitant administration of drugs that inhibit this enzyme (e.g. quinidine, paroxetine, fluoxetine and bupropion) may cause increased plasma levels of desglymidodrine with a potential risk of increased adverse events.

Potential effect of midodrine on other drugs:

Midodrine is an inhibitor of CYP2D6 and may affect the metabolism of other drugs. This may be of clinical relevance for active substances that are mainly metabolized by CYP2D6, e.g. tricyclic antidepressants, beta blockers, selective serotonin reuptake inhibitors (SSRI), antiarrhythmics (including class 1A, 1B and 1C) and monoamine oxidase inhibitors (MAO inhibitors) type B, especially if the active substance also has a narrow therapeutic index.

Falsely elevated plasma metanephrine:

This potential for interference should be considered in cases where patients taking midodrine require biochemical investigation for potential pheochromocytomas and paragangliomas.

Pregnancy and Lactation:

MIDORIN-10 should not be used during pregnancy & breast-feeding.

Undesirable effects:

The most frequent and very common adverse reactions related to midodrine hydrochloride therapy are piloerection, pruritus of the scalp and dysuria.

Below listed side-effects also may occur, while using MIDORIN-10.

Psychiatric disorders: Sleep disorders, Insomnia, Anxiety, Confusional state.

Nervous system disorders: Paraesthesia of the scalp, eadache, Restlessness, Excitability, Irritability.

Cardiac Disorders: Reflex bradycardia, Tachycardia, Palpitations.

Vascular Disorders: Supine hypertension (dose dependent effect).

Gastrointestinal disorders: Nausea, Dyspepsia, Stomatitis, Abdominal pain, Vomiting, Diarrhoea.

Hepatobiliary disorders: Abnormal hepatic function, Raised liver enzymes.

Skin and subcutaneous tissue disorders: Piloerection (goose bumps), Pruritus of the Scalp, Pruritus, Chills, Flushing Rash.

Renal and Urinary Disorders: Dysuria, Urinary retention, Urinary urgency.

Overdose:

The following symptoms may occur: hypertension, piloerection (goose bumps) and feeling cold, bradycardia (reflex bradycardia) and urinary retention.

Treatment: In addition to the main general "life support" measures, induced vomiting and the administration of an α -sympatholytic agent (e.g. nitroprusside, phentolamine, nitroglycerine) is recommended, based on the pharmacology of the drug.

Bradycardia and bradycardic conduction disturbances can be blocked by atropine.
The active metabolite desglymidodrine is dialysable.

Storage:

Store below 30°C in dry place. Protect from light.

Keep the medicines out of reach of children.

Presentation:

100 Tablets are packed in a Jar.

Manufactured by:

