Midodrine HCl Tablets, USP

Midodrine HCl Tablets, USP (2.5 mg, 5 mg and 10 mg tablets) are for oral administration.

**DOSAGE AND ADMINISTRATION**

**Symptomatic Orthostatic Hypotension**

**Adults**

The recommended starting dose of midodrine HCl Tablets, USP is 2.5 mg each morning. The dose may be increased at 2-week intervals as needed up to a maximum daily dose of 20 mg.

**Pediatric Patients**

The safety and effectiveness of midodrine HCl Tablets, USP in pediatric patients have not been established.

**SIDE EFFECTS**

The most common adverse reactions associated with midodrine therapy are increases in systolic and diastolic blood pressure. Other reactions include dry mouth, increased sweating, palpitations, and tachycardia. These reactions are generally mild and subside at lower dosages.

**PRECAUTIONS**

**Clinical Experience**

Midodrine HCl Tablets, USP have been studied in over 1,000 patients in clinical trials. Midodrine use has not been studied in patients with hepatic impairment. Midodrine should be used with caution in patients with hepatic impairment, as the liver has a role in the metabolism of midodrine.

**Special Populations**

**Renal Impairment**

Midodrine HCl Tablets, USP have not been studied in patients with renal impairment. Midodrine HCl Tablets, USP should be used with caution in patients whose lives are considerably impaired despite standard clinical care, including non-pharmacological therapy.

**Depression**

Midodrine HCl Tablets, USP should be used with caution in patients with a history of depression or suicidal tendencies, as these conditions may be exacerbated by the use of midodrine HCl Tablets, USP.

**Intraocular Pressure and Glaucoma**

Midodrine HCl Tablets, USP should be used with caution in patients with intraocular pressure and glaucoma.
Midodrine has been used in patients consistently treated with a sympatholytic drug, either alone or in combination, in a dosage range of 2.5 to 10 mg daily. In such patients, the administration of oral midodrine had no significant effect on blood pressure. However, the incidence of headache, palpitation, and flushing increased in these patients, and these effects were dose-related. Midodrine increased the rate of embryo resorption, reduced fetal body weight, and caused fetotoxicity in rats and rabbits. No adverse effect on the fetus was observed in a study using desglymidodrine, a metabolite of midodrine, in rats and rabbits. Therefore, midodrine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

The most potentially serious adverse reaction associated with midodrine therapy is supine hypertension. The use of drugs that stimulate alpha-adrenergic receptors (e.g., phenylephrine, pseudoephedrine, ephedrine, terazosin, and doxazosin) can antagonize the effects of midodrine.

As with any drug, care should be exercised in the selection and dosing of patients, particularly the elderly, and when comparing males vs. females, suggesting dose modifications for these groups are necessary. The blood levels of midodrine and desglymidodrine were similar when comparing levels in patients 65 or older vs. younger than 65 and when comparing males vs. females, suggesting dose modifications for these groups are necessary. Recommendations for use in children have not been adequately studied.