

Abbreviated prescribing information of Harnal D

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Version: 003

Composition:

Tamsulosin HCl

Indications:

Bladder outlet obstruction associated with benign prostatic hyperplasia.

Dosage:

0.2 mg once daily.

Administration:

Take after meals. Place on the tongue & allow to dissolve. Then, swallow w/ saliva or water.

Contraindications:

Patients with known hypersensitivity to this drug or any of the components of this product.

Precautions:

Precautions concerning indications:

1. Caution should be paid to the point that the treatment with this product is a symptomatic treatment, not causal therapy. If the expected effect is not noted, surgical therapy or other alternative procedures should be considered.
2. The diagnosis and treatment of benign prostatic hyperplasia should be carried out in reference to the latest information such as academic societies' guidelines, etc.

Precautions concerning dosage and administration:

Elderly patients are more likely to experience renal dysfunction. Such patients should be carefully monitored. If expected effect is not noted at dosage of 0.2mg, the dose should not be increased further, and other appropriate measures should be taken.

Important precautions:

1. Overdosage may cause a decrease in blood pressure. Use with caution concerning dosage.
2. Blood pressure in the orthostatic position may decrease. Patients must be watched for any changes in blood pressure occurring with postural change.
3. Since this product may induce symptoms such as dizziness, patients should be instructed to exercise caution against engaging in hazardous activities, such as working at altitudes or driving a car.
4. Before the start of treatment, patients should be asked whether they are taking any antihypertensive agents. If any such drugs are used, changes in blood pressure should be monitored closely. If a decrease in blood pressure is observed, appropriate measures such as a reduction in the dose or discontinuation of this product should be taken.

Precautions concerning patients with specific backgrounds:

1. Patients with Complication or History of Diseases, etc.:

1.1 Patients with orthostatic hypotension:

Symptoms may be aggravated.

1.2 Patients with a past history of hypersensitivity to sulfonamide:

An allergic reaction may occur.

2. Patients with Renal Impairment:

2.1 Patients with severe renal impairment:

Plasma concentration of this product may be increased.

3. Patients with Hepatic Impairment:

3.1 Patients with severe hepatic function disorder:

Plasma concentrations of this product may be increased.

4. Geriatric Use:

Elderly patients often have reduced renal function.

Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.):

Tamsulosin is extensively metabolized, mainly by CYP3A4 and CYP2D6.

1. Antihypertensives:

Signs, Symptoms and Treatment: Since orthostatic hypotension may occur, take precautions by decreasing doses.

Mechanism and Risk Factors: Patients who take antihypertensives may experience a decrease in blood pressure when they stand up.

2. Phosphodiesterase-5 inhibitors e.g. Sildenafil citrate, Vardenafil HCl hydrate, etc.:

Signs, Symptoms and Treatment: It has been reported that concomitant use of phosphodiesterase-5 inhibitors and this product may cause hypotension.

Mechanism and Risk Factors: Since this product exhibits an α -blocking activity, the vasodilatory hypotensive action of phosphodiesterase-5 inhibitors may be enhanced by concomitant use.

3. CYP3A4 strong inhibitors*, Ketoconazole, Itraconazole, Ritonavir, Atazanavir sulfate, Indinavir sulfate, Nelfinavir, Saquinavir, mesylate, Clarithromycin, Telithromycin:

Signs, Symptoms and Treatment: Concurrent administration may enhance the adverse events.

Mechanism and Risk Factors: There is a potential for significant increase in tamsulosin exposure when Harnal[®] D is co-administered with a strong CYP3A4 inhibitor.

*Harnal[®] D should not be used in combination with strong inhibitors of CYP3A4 in patients known to be CYP2D6 poor metabolizers.

Precautions Concerning Use:

Precautions concerning the Dispensing of the Drug:

1. For drugs that are dispensed in a press-through package (PTP), instruct the patient to remove the drug from the package prior to taking this product. If the PTP sheet is swallowed, the sharp corners of the sheet may puncture the esophageal mucosa, resulting in severe complications such as **mediastinitis**.
2. Patients should be instructed not to chew the tablets. Prolonged release particles of tamsulosin hydrochloride are contained in this product. Crushing or chewing the tablets may destroy the prolonged release particles and may cause changes in pharmacokinetics.
3. Since the tablet can be soaked with saliva on the tongue and can be disintegrated, the tablet can be swallowed without using water. Also, this product can be taken with water.
4. The tablet should not be taken without water if the patient is in a lying position.

Other Precautions:

Information Based on Clinical Uses:

Intraoperative floppy iris syndrome has been reported in patients currently taking or having a history of treatment with α_1 -blockers.

Precautions for Handling:

For drugs that are dispensed in a press-through package (PTP), the quality of this product is maintained by an aluminum pack. After opening the aluminum pack, store away from moisture.

Adverse Reactions:

Since the following adverse reactions may occur, patient should be observed carefully. If any abnormal findings are observed, appropriate measures such as drug discontinuation, etc. should be taken.

1. Clinically Significant Adverse Reactions:

1.1 Syncope/unconsciousness (incidence unknown):

Transient unconsciousness, etc. due to decreased blood pressure may occur.

1.2 Hepatic function disorder, jaundice (incidence unknown, each):

AST increased, ALT increased or jaundice, etc. may occur.

2. Other Adverse Reactions:

Psyconeurologic: $\geq 0.1\%$, $< 5\%$: Dizziness, Swaying feeling. *Incidence unknown:* Dizziness on standing up, Headache, Sleepiness, Bad mood, Numbness.

Cardiovascular: $\geq 0.1\%$, $< 5\%$: Tachycardia. *Incidence unknown:* Blood pressure decreased, Orthostatic hypotension, Palpitations, Arrhythmia.

Hypersensitivity: $\geq 0.1\%$, $< 5\%$: Rash. *Incidence unknown:* Itching, Urticaria, Erythema multiforme, Dermatitis exfoliative, Angiodema.

Gastrointestinal: $\geq 0.1\%$, $< 5\%$: Stomach discomfort, Queasy, Vomiting, Stomach heaviness, Gastralgia, Anorexia, Dysphagia. *Incidence unknown:* Thirst, Constipation, Diarrhoea.

Others: $\geq 0.1\%$, $< 5\%$: Burning sensation of pharynx, General malaise. *Incidence unknown:* Nasal congestion, Oedema, Urinary incontinence, Dysgeusia, Gynaecomastia, Priapism, Ejaculation disorder, Intraoperative floppy iris syndrome, Vision blurred, Visual impairment, Hot Flush, Feeling hot, Burning sensation, Epistaxis.

Full prescribing information is available upon request.