DYNAPRES 0.4

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

Abbreviated Prescribing information for DYNAPRES 0.4 (Tamsulosin Hydrochloride Prolonged Release Capsules I.P. 0.4 mg) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: The symptoms associated with benign prostatic hyperplasia (BPH) are related to bladder outlet obstruction, which is comprised of two underlying components: static and dynamic. The static component is related to an increase in prostate size caused, in part, by a proliferation of smooth muscle cells in the prostatic stroma. However, the severity of BPH symptoms and the degree of urethral obstruction do not correlate well with the size of the prostate. The dynamic component is a function of an increase in smooth muscle tone in the prostate and bladder neck leading to constriction of the bladder outlet. Smooth muscle tone is mediated by the sympathetic nervous stimulation of alpha1 adrenoceptors, which are abundant in the prostate, prostatic capsule, prostatic urethra, and bladder neck. Blockade of these adrenoceptors can cause smooth muscles in the bladder neck and prostate to relax, resulting in an improvement in urine flow rate and a reduction in symptoms of BPH. Tamsulosin, an alpha1 adrenoceptor blocking agent, exhibits selectivity for alpha1 receptors in the human prostate. At least three discrete alpha1 adrenoceptor subtypes have been identified: alpha1A, alpha1B, and alpha1D; their distribution differs between human organs and tissue. Approximately 70% of the alpha1 receptors in the human prostate are of the alpha1A subtype. DYNAPRES capsules are not intended for use as an antihypertensive drug.

INDICATIONS: DYNAPRES 0.4 capsules are indicated for the signs and symptoms of benign prostatic hyperplasia.

DOSAGE AND ADMINISTRATION: DYNAPRES capsules 0.4 mg once daily is recommended as the dose for the treatment of the signs and symptoms of BPH. It should be administered approximately one-half hour following the same meal each day. DYNAPRES capsules should not be crushed, chewed or opened. For those patients who fail to respond to the 0.4 mg dose after 2 to 4 weeks of dosing, the dose of DYNAPRES capsules can be increased to 0.8 mg once daily. DYNAPRES capsules should not be crushed, chewed or opened.

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If DYNAPRES capsules administration is discontinued or interrupted for several days at either the 0.4 mg or 0.8 mg dose, therapy should be started again with the 0.4 mg once-daily dose. *Method of administration:* Oral administration.

CONTRAINDICATION: DYNAPRES capsules are contraindicated in patients known to be hypersensitive to tamsulosin hydrochloride or any component of DYNAPRES capsules. Reactions have included skin rash, urticaria, pruritus, angioedema, and respiratory symptoms.

WARNINGS & PRECAUTIONS The signs and symptoms of orthostasis (postural hypotension, dizziness, and vertigo) were detected more frequently in DYNAPRES capsule-treated patients than in placebo recipients. As with other alpha adrenergic blocking agents there is a potential risk of syncope Patients beginning treatment with DYNAPRES capsules should be cautioned to avoid situations in which injury could result should syncope occur.

DRUG INTERACTIONS: DYNAPRES capsules 0.4 mg should not be used with strong inhibitors of CYP3A4 (e.g., ketoconazole). DYNAPRES capsules should be used with caution in combination with moderate inhibitors of CYP3A4 (e.g., erythromycin), in combination with strong (e.g., paroxetine) or moderate (e.g., terbinafine) inhibitors of CYP2D6, or in patients known to be CYP2D6 poor metabolizers, particularly at a dose higher than 0.4 mg (e.g., 0.8 mg). Concomitant use of PDE5 inhibitors with tamsulosin can potentially cause symptomatic hypotension. DYNAPRES capsule is administered concomitantly with cimetidine, other Alpha Adrenergic Blocking Agents, warfarin, nifedipine, atenolol, enalapril, digoxin and theophylline, furosemide.

ADVERSE REACTIONS: Decreased blood pressure when changing positions. DYNAPRES capsules may cause a sudden drop in blood pressure upon standing, especially after the first dose or when changing doses. Symptoms may include**:** fainting, dizziness, lightheadedness. Change positions slowly from lying down to sitting up or from a sitting to a standing position until you learn how you react to DYNAPRES capsules. If you begin to feel dizzy, sit or lie down until you feel better. If the symptoms are severe or do not improve, call your doctor. Allergic reactions may include: rash, itching, hives. Rare and more serious allergic reactions may also occur. Get medical help right away if you have any of the following reactions: swelling of face, tongue, or throat, difficulty breathing, blistering of the skin. Painful erection that will not go away DYNAPRES capsules can cause a painful erection (priapism), which cannot be relieved by having sex. If this happens, get medical help right away. If priapism is not treated, you may not be able to get an erection in the future. Eye problems during cataract or glaucoma surgery. During cataract or glaucoma surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you take or have taken DYNAPRES capsules. If you need to have cataract or glaucoma surgery, be sure to tell your surgeon if you take or have taken DYNAPRES capsules. Common side effects of DYNAPRES capsules may include: runny nose, dizziness, decrease semen.

MARKETED BY:

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(Additional information is available on request)