DYNAPRES D

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

Abbreviated Prescribing information for **DYNAPRES D**

(Tamsulosin Hydrochloride Extended Release & Dutasteride Tablets) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action:

Dutasteride-tamsulosin is a combination of two drugs: dutasteride, a dual 5 α- reductase inhibitor (5 ARI) and tamsulosin hydrochloride, an antagonist of α1a and α1d adrenoreceptors. These drugs have complementary mechanisms of action that rapidly improve symptoms, urinary flow and reduce the risk of acute urinary retention (AUR) and the need for BPH related surgery.

Dutasteride inhibits both type 1 and type 2, 5 alpha-reductase isoenzymes, which are responsible for the conversion of testosterone to dihydrotestosterone.

INDICATIONS: It is indicated for the treatment of benign prostate hyperplasia.

DOSAGE AND ADMINISTRATION: As directed by the Physician.

CONTRAINDICATION: Women, children and adolescents, Patients with hypersensitivity to dutasteride, other 5-alpha reductase inhibitors, tamsulosin (including tamsulosin-induced angio-edema) or any of the other excipients, Patients with a history of orthostatic hypotension, Patients with severe hepatic impairment.

WARNINGS & PRECAUTIONS:

Exposure of Women-Risk to Male Foetus. Dutasteride is absorbed through the skin. Therefore, women who are pregnant or may be pregnant should not handle Dutasteride tablets because of the possibility of absorption of Dutasteride and the potential risk of foetal anomaly to a male foetus, ***Prostate cancer and high grade tumours*** The REDUCE study, a 4-year, multicentre, randomised, double-blind, placebo controlled study investigated the effect of dutasteride 0.5 mg daily on patients with a high risk for prostate cancer, ***Prostate specific antigen (PSA)*** Serum prostate-specific antigen (PSA) concentration is an important component in the detection of prostate cancer, ***Cardiovascular adverse events*** In two 4-year clinical studies, the incidence of cardiac failure (a composite term of reported events, primarily cardiac failure and congestive cardiac failure) was marginally higher, ***Breast neoplasia*** There have been rare reports of male breast cancer reported in men taking dutasteride in clinical trials and during the post-marketing period, ***Renal impairment*** The treatment of patients with severe renal impairment (creatinine clearance of less than 10 ml/min) should be approached with caution as these patients have not been studied. ***Hypotension*** Orthostatic: As with other alpha1- adrenoceptor antagonists, a reduction in blood pressure can occur during treatment with tamsulosin, as a result of which, rarely, syncope can occur. ***Hepatic impairment*** Dutasteride/Tamsulosin hydrochloride has not been studied in patients with liver disease.

DRUG INTERACTIONS: ***PDE5 inhibitors*** (used to help achieve or maintain an erection) such as vardenfil, sildenafil citrate and tadalafil, ***verapamil or diltiazem*** (for high blood pressure), ***ritonavir or indinavir*** (for HIV), ***itraconazole or ketaconazole*** (for fungal infections), ***nefazodone*** (an antidepressant),**cimetidine** (for stomach ulcers), ***warfarin*** (for blood clotting), ***erythromycin*** (an

antibiotic used to treat infections), ***paroxetine*** (an antidepressant), ***terbinafine*** (used to treat fungal infections), ***diclofenac*** (used to treat pain and in_ammation).

ADVERSE REACTIONS: Allergic reaction, Dizziness, light-headedness and fainting, Serious skin reactions, breast enlargement or tenderness, Cardiac failure, Orthostatic hypotension, Stevens- Johnson syndrome.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

IN/DYNAPRES D 0.4 mg + 0.5 mg /JUN-23/01/ABPI

(Additional information is available on request)