

U`vgmytjvwmb nvB#W#v#K-vivBW BDGmwc 0.4 wgMÖv Ges WzUv#÷ivBW BDGm



Tamsulosin Hydrochloride USP 0.4 mg and Dutasteride USP 0.5 mg

উপস্থাপন

cÖwZ K`vcmyj-G Av#Q U`vgmytjvwmb nvB#W#v#K-vivBW BDGmwc 0.4 wgMÖv-Gi wc#jUm# Ges WzUv#÷ivBW BDGmwc 0.5 wgMÖv|

নির্দেশনা

gvSvwi t_#K gvivZ#K webvBb tCÖv#÷wUK nvB#W#v#K-vivBW (wewcGBP) Gi Dcm#M@i wPwKrmvq|

gvSvwi t_#K gvivZ#K wewcGBP Gi Dcm#M@ Av#Q Ggb tivMx#i t#i#i GwKDU BDwibvix wi#UbkB Ges A#`zvcPv#ii SzuwK n#v#m|

মাত্রা ও প্রয়োগবিধি

cÖv# eq` (AwaK eq`mn)t wb#`wkZ gv#v n#`Q 1wU tCÖv÷v#Kqvi-wW K`vcmyj (U`vgmytjvwmb nvB#W#v#K-vivBW 0.4 wgMÖv Ges WzUv#÷ivBW 0.5 wgMÖv) cÖwZw`b GKB mg#qi Avnv#ii Avav N#v cil m#u`Y@ K`vcmyj MjatKiY Ki#Z n#e Ges wPev#bv ev tLjv hv#e bv| cÖ#hvR` t#i#i, wPwKrmv mnR Kivi j#i#i hviv GKB m#i/2 U`vgmytjvwmb nvB#W#v#K-vivBW Ges WzUv#÷ivBW w`#q Avjv`v Avjv`v wPwKrmv wb#`Qb Zv#i t#i#i tCÖv÷v#Kqvi-wW K`vcmyj w`#q wPwKrmv cÖwZ`vcb Kiv th#Z cv#i| wPwKrmvMZfv#e cÖ#qvRbxq t#i#i U`vgmytjvwmb nvB#W#v#K-vivBW A_ev WzUv#÷ivBW Gi GKK wPwKrmv wb#`Qb Ggb tivMx#i t#i#i tCÖv÷v#Kqvi-wW K`vcmyj w`#q mivmwi wPwKrmv cÖwZ`vcb Kiv th#Z cv#i| U`vgmytjvwmb-WzUv#÷ivBW dvg@v#KvKvB#bwUKm-Gi Dci e,`xq l hK...Z AKvh@KvixZvi cÖfve wb#q M#elYv Kiv nqwb| Z_vvc g_y t_#K gvSvwi tivMx#i t#i#i Aek`B mveavvZv Aej#Ab Ki#Z n#e|

প্রতি নির্দেশনা

gwnjv, wk# Ges eqtmwÜKv#ji t#i#i, WzUv#÷ivBW, Ab`vb` 5 Avjdv wiWvK#Um BbwnweUi, U`vgmytjvwmb (U`vgmytjvwmb BbwwDmW G`vbwRiB#Wgv mn) ev Ab`vb` th tKvb Dcv`vb Gi cÖwZ AwZ m#e`bkj tivMx#i t#i#i U`vgmytjvwmb-WzUv#÷ivBW Gi th#S`_e`envi wb#`wkZ bq| সাবানভা ও সতর্কতা

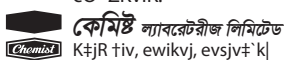
m#Cve` cÖwZKj NUbvi (ü`h#z#i AK...ZKvh@Z mn) SzuwK te#o hvlqvi t#i#i mZK@Zv Aej#Ab K#i tivMxi myweav SzuwKi g~j`vq#bi ci Ges GKK wPwKrmv mn weKi wPwKrmvi my#hvM myweav we#ePbvi ci th#S`_ wPwKrmv wba@vwiZ Kiv DwPZ| U`vgmytjvwmb mn Ab`vb` Avjdv GwW#bvwR@K eowKs G#R.U Gi cvkvcvwk wcvWBS BbwnweUi (thgb: wmj#Wbvwjd, UvWvjwjd, fiv#Wbvwjd) GK#i e`envi#ii t#i#i mZK@Zv MÖNy Kiv Dcw`ö| Avjdv GwW#bvwR@K eowKvim Ges wcvWBS BbwnweUi Dfqb i#bvjx cÖmviY K#i weavq i#Pvc Kwg#q t`q| GB `yB tKÖYxi lly#ai GK#i e`envi i#Pvc Kwg#q w`#Z cv#i| U`vgmytjvwmb Øviv c~#e@ wPwKrmv K#i#Qb A_ev Ki#Qb Ggb tivMx#i Qvwb A#`zvcPvi B:U#vAcv#iUf d~wc AvbWk wmb#W#vg (AvBGdAvBGM) cwijw#Z n#q#Q| wQ`#hy` K`vcmyj Gi t#i#i: th#nZ WzUv#÷ivBW Pg@ Øviv t#kwlZ nq, tm#nZz gwnjv, wk#i wK#kvi wK#kvi#i t#i#i Aek`B wQ`#hy` K`vcmyj Gi m#`ük@ Gov#Z n#e| hw` wQ`#hy` K`vcmyj Øviv m#`ük@ nq, tm#i#i Avmvs#i `vb mvevb I cvwb Øviv Awej#Ab t#S`Z Kiv DwPZ|

অন্যান্য গুরুত্বপূর্ণ সতর্কতা

i#Pvc Kwg#q w`#Z cv#i Ggb RvZxq llya, thgb Abyf,wZbvK llya, wcvWBS BbwnweUim Ges Ab`vb` Avjdv-1 G`vwW#bvwR@K eowKvim Gi mv#_ U`vgmytjvwmb-nvB#W#v#K-vivBW GK#i e`envi#i wba#e i#Pvc cÖfve evwo#q w`#Z cv#i| WzUv#÷ivBW Gi mv#_ wmlqvBwcv`aG4 GbRvBg Gi kw`kvjx BbwnweUi RvZxq llya (wi#Uvbwvfi, BbwWbvf, tbdv#Rv#Wvb, BU#v#KvbwRj, wK#Uv#KvbwRj Gi tgSwlK MÖNy) `xN#w`b GK#i e`envi#i WzUv#÷ivBW Gi Nbgvli#` evwo#q w`#Z cv#i| Ab`vb` Avjdv-1 G`vwW#bvwR@K eowKvim Gi mv#_ U`vgmytjvwmb-WzUv#÷ivBW Gi th#S`_ wPwKrmv GK#i e`envi Kiv DwPZ bq| U`vgmytjvwmb nvB#W#v#K-vivBW (0.4 wgMÖv) Ges w#m#gUwWb (400 wgMÖv cÖwZ 6 N#v cici 6 w`b hver) GK#i e`envi#i U`vgmytjvwmb-nvB#W#v#K-vivBW Gi AcmviY (26%) Kwg#q t`qv Ges GBDwm (44%) evwo#q t`evi djvdj cvlqv tM#Q| U`vgmytjvwmb-WzUv#÷ivBW Gi th#S`_ e`envi#ii cvkvcvwk w#m#gUwWb ev lqvdivwib GK#i e`envi#i t#i#i mZK@Zv Aej#Ab Kiv DwPZ|

গর্ভাবস্থায় এবং স্তন্যদানকালে ব্যবহার

U`vgmytjvwmb-WzUv#÷ivBW Gi th#S`_ wPwKrmv gwnjv#i t#i#i e`envi wb#`wkZ bq| Mf@ve`vq, `Ib`vbKv#j Ges cÖRbb Gi t#i#i U`vgmytjvwmb-WzUv#÷ivBW Gi th#S`_ wPwKrmv cÖfve AbymÜv#bi Rb` cÖ`ZKviK:



Presentation

Each capsule contains pellets of Tamsulosin Hydrochloride USP 0.4 mg and Dutasteride USP 0.5 mg.

Indications

Treatment of moderate to severe symptoms of Benign Prostatic Hyperplasia (BPH). Reduction in the risk of acute urinary retention and surgery in patients with moderate to severe symptoms of BPH.

Dosage and administration

Adults (including elderly): The recommended dose is one Prostacare-D capsule (Tamsulosin Hydrochloride 0.4 mg & Dutasteride 0.5 mg) taken orally approximately 30 minutes after the same meal each day. The capsules should be swallowed whole and not chewed or opened. Where appropriate, Prostacare-D capsule may be used to substitute concomitant Tamsulosin Hydrochloride and Dutasteride in existing dual therapy to simplify treatment. Where clinically appropriate, direct change from Tamsulosin Hydrochloride or Dutasteride monotherapy to Prostacare-D capsule may be considered. The effect of renal & hepatic impairment on Tamsulosin - Dutasteride pharmacokinetics has not been studied. So caution should be used in patients with mild to moderate renal & hepatic impairment.

Contra-indications

Tamsulosin-Dutasteride combination is contra-indicated in women and children and adolescents, patients with hypersensitivity to Tamsulosin (including Tamsulosin-induced angio-edema), Dutasteride (including other 5-alpha reductase inhibitors) or any ingredient in the formulation.

Precautions and warnings

Combination therapy should be prescribed after careful benefit risk assessment due to the potential increased risk of adverse events (including cardiac failure) and after consideration of alternative treatment options including monotherapies. Caution is advised when alpha adrenergic blocking agents including Tamsulosin are coadministered with PDE5 inhibitors (e.g. sildenafil, tadalafil, vardenafil). Alpha adrenergic blockers and PDE5 inhibitors are both vasodilators that can lower blood pressure. Intraoperative Floppy Iris Syndrome (IFIS) has been observed during cataract surgery in some patients on or previously treated with Tamsulosin. Leaking Capsule: Dutasteride is absorbed through the skin, therefore, women, children and adolescents must avoid contact with leaking capsules. If contact is made with leaking capsules, the contact area should be washed immediately with soap and water.

Drug interactions

Concomitant administration of Tamsulosin Hydrochloride with drugs which can reduce blood pressure, including anaesthetic agents, PDE5 inhibitors and other alpha-1 adrenergic blockers could lead to enhanced hypotensive effects. Long-term combination of Dutasteride with drugs that are potent inhibitors of the enzyme CYP3A4 (e.g. ritonavir, indinavir, nefazodone, itraconazole, ketoconazole administered orally) may increase serum concentrations of Dutasteride. Tamsulosin-Dutasteride should not be used in combination with other alpha-1 adrenergic blockers. Concomitant administration of Tamsulosin Hydrochloride (0.4 mg) and Cimetidine (400 mg every six hours for six days) resulted in a decrease in the clearance (26%) and an increase in the AUC (44%) of Tamsulosin Hydrochloride. Caution should be used when Tamsulosin-Dutasteride is used in combination with Cimetidine or Warfarin.

Use in pregnancy and lactation

Tamsulosin-Dutasteride combination is contra-indicated for use by women. There have been no studies to investigate the effect of Tamsulosin-Dutasteride combination on pregnancy, lactation and fertility. Administration of Tamsulosin Hydrochloride to pregnant female rats and rabbits showed no evidence of fetal harm. Lactation: It is not known whether Tamsulosin Or Dutasteride are excreted in human milk.

Side effect

The most common side effects are Dizziness, Headache, Nausea, Vomiting, Syncope, Palpitations, Constipation, Diarrhoea, Ejaculation disorder, Breast disorder, Weakness.

Overdose

No data are available with regard to over dosage of Tamsulosin-Dutasteride combination.

Storage

Protected from light, Store at temperature within 30°C. Keep out of reach of children.

Packaging quantity

Prostacare-D capsule: Carton containing 16 capsules in alu-alu blisters.

Manufactured by:

