

JALYN (dutasteride/tamsulosin)

Take one pill a day 1/2 hr after the same meal.

JALYN, a combination of dutasteride, a 5 alpha-reductase inhibitor, and tamsulosin, an alpha-adrenergic antagonist, is indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate.

Important Safety Information for JALYN

JALYN is contraindicated in

- Women who are or may become pregnant
- Pediatric patients
- Patients with clinically significant hypersensitivity (eg, serious skin reactions, angioedema, urticaria, pruritus, respiratory symptoms) to dutasteride, other 5 alpha-reductase inhibitors, tamsulosin, or any other component of JALYN

Women who are or may become pregnant should not handle JALYN.

Dutasteride, a component of JALYN, is absorbed through the skin and could result in unintended fetal exposure.

Orthostatic Hypotension

As with other alpha-adrenergic antagonists, a drop in blood pressure (postural hypotension, dizziness, and vertigo) may occur in patients treated with tamsulosin-containing products, including JALYN. Patients starting treatment with JALYN should be cautioned to avoid situations, such as driving and other potentially hazardous tasks, where syncope could result in injury.

Effects on Prostate-specific Antigen (PSA) and the Use of PSA in Prostate Cancer Detection

Coadministration of dutasteride with tamsulosin resulted in similar changes to serum PSA as with dutasteride monotherapy. Dutasteride reduced serum PSA

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concentration by approximately 50% within 3 to 6 months of treatment. This decrease was predictable over the entire range of PSA values in patients with symptomatic BPH, although it may vary in individuals. Dutasteride-containing products, including JALYN, may also cause decreases in serum PSA in the presence of prostate cancer. To interpret serial PSAs in men treated with a dutasteride-containing product, including JALYN, a new baseline PSA should be established at least 3 months after starting treatment and PSA monitored periodically thereafter. Any confirmed increase from the lowest PSA value while on a dutasteride-containing product, including JALYN, may signal the presence of prostate cancer and should be evaluated, even if PSA levels are still within the normal range for men not taking a 5 alpha-reductase inhibitor. Noncompliance with JALYN may also affect PSA test results.