

客户名称	人福普克药业(武汉)有限公司	产品名称	度他雄胺0.5mg 30ct/90ct说明书(正)
颜色标准	黑	成品尺寸	533X305mm
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HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DUTASTERIDE CAPSULES safely and effectively. See full prescribing information for DUTASTERIDE CAPSULES.

DUTASTERIDE capsules, for oral use

Initial U.S. Approval: 2001

RECENT MAJOR CHANGES

Warnings and Precautions, Evaluation for Other Uterine Diseases (5.3) 03/2012

INDICATIONS AND USAGE
Dutasteride capsules is a 5 α -reductase inhibitor indicated for the treatment of symptomatic benign prostate hyperplasia (BPH) in men with an enlarged prostate to (1,1)

- improve symptoms,
- reduce the risk of acute urinary retention, and
- reduce the risk of the need for BPH-related surgery.

Dutasteride capsules in combination with the alpha adrenergic antagonist, tamsulosin, is indicated for the treatment of symptomatic BPH in men with an enlarged prostate. (1,2)

LIMITATIONS OF USE: Dutasteride capsules is not approved for the prevention of prostate cancer. (1,2)

DOSAGE AND ADMINISTRATION

Monotherapy: 0.5 mg once daily. (2,1)

Combination with tamsulosin: 0.5 mg once daily and tamsulosin 0.4 mg once daily. (2,2)

Dosing considerations: Swallow whole. May take with or without food. (2)

DOSE FORMS AND STRENGTHS

0.5-mg capsules (3)

CONTRAINDICATIONS

Pregnancy and women of childbearing potential. (4, 5, 6, 8)

Pediatric patients. (4)

Patients with previously demonstrated, clinically significant hypersensitivity (e.g., serious skin reactions; angioedema) to dutasteride capsules or other 5 α -reductase inhibitors. (4)

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

1.1 Monotherapy

Dutasteride capsules are indicated for the treatment of symptomatic benign prostate hyperplasia (BPH) in men with an enlarged prostate to:

- Improve symptoms,
- reduce the risk of acute urinary retention, and
- reduce the risk of the need for BPH-related surgery.

1.2 Combination with Alpha-adrenergic Antagonist

Dutasteride capsules in combination with the alpha-adrenergic antagonist, tamsulosin, is indicated for the treatment of symptomatic BPH in men with an enlarged prostate. (1,2)

DOSAGE AND ADMINISTRATION

Monotherapy: 0.5 mg once daily. (2,1)

Combination with tamsulosin: 0.5 mg once daily and tamsulosin 0.4 mg once daily. (2,2)

Dosing considerations: Swallow whole. May take with or without food. (2)

DOSE FORMS AND STRENGTHS

0.5-mg capsules (3)

CONTRAINDICATIONS

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

5.2 Increased Risk of High-grade Prostate Cancer

5.3 Non-clinical Toxicology

5.4 Clinical Studies

5.5 Effectiveness Research

6 OTHER INFORMATION

6.1 Clinical Trials Experience

6.2 Postmarketing Experience

7 DRUG INTERACTIONS

7.1 PSA Monitoring

7.2 Alpha Adrenergic Antagonists

7.3 Calcium Channel Antagonists

7.4 Cholestyramine

7.5 Digoxin

7.6 Warfarin

FULL PRESCRIBING INFORMATION

5 WARNINGS AND PRECAUTIONS

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

5.2 Increased Risk of High-grade Prostate Cancer

5.3 Non-clinical Toxicology

5.4 Exposure of Women—Risk to Male Fetus

5.5 Blood Donations

5.6 Use in Specific Populations

5.7 Use in Special Populations (8.1)

5.8 Use in Pediatric Patients (8.4)

5.9 Patients with Previously Demonstrated, Clinically Significant Hypersensitivity (e.g., serious skin reactions; angioedema) to dutasteride or other 5 α -reductase inhibitors. (see Adverse Reactions (6.2)).

5.10 Use in Specific Populations (8.10)

5.11 Use in Specific Populations (8.11)

5.12 Use in Specific Populations (8.12)

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