METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

009709-TDS-ENG-2025

DUTASTERIDA (EUR. PH.)		
DESCRIPTION DCI: dutasteride	DESCRIPTION DOE: DUTASTERIDA	
CAS Nº: 164656-23-9	EC Nº: 638-758-5	AEMPS CODE: 2893A
MOL. WEIGHT: 528,53	MOL. FORMULA: C27H30F6N2O2	ARTICLE CODE: 009709

ATTRIBUTES	SHOULD BE
Appearance	White or pale yellow powder
Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble or sparingly soluble in anhydrous ethanol
Identification A	Complies
Identification B	Complies
Specific optical rotation	+33.0 / +39.0
Related substances	
Method A	
Impurity F	=< 0.4 %
Impurity E	=< 0.3 %
Impurity G	=< 0.3 %
Impurity A	=< 0.2 %
Impurity C	=< 0.2 %
Impurity B	=< 0.15 %
Unspecified impurities	=< 0.10 %
Method B	
Impurity I	=< 0.5 %
Impurity H	=< 0.3 %
Unspecified impurities after Dutasteride	=< 0.10 %
Total impurities	=< 1.5 %
Water	=< 0.2 %
Sulfated ash	=< 0.1 %
Assay	97.0 - 102.0 %

COMPLIES WITH

European Pharmacopeia 11.0

STORAGE

Keep the container tightly closed. Store in a cool and dry place.

REMARKS

Dutasteride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

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All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Properties and uses
DUTASTERIDE is an inhibitor of testosterone 5-alpha reductase.
The time until reaching the maximum serum concentrations is 1 - 3 h. The absolute bioavailability is approximately 60%, and is not affected by food. It has a large volume of distribution and binds with high affinity to plasma proteins (> 99.5%). Serum concentrations reach 65% of the steady state concentration after 1 month and approximately 90% after 3 months. It is extensively metabolized in vivo. The 1.0 - 15.4% of the administered dose is excreted as DUTASTERIDE without modifying in faeces. The rest is excreted in the faeces as metabolites. It is not known if it is excreted in breast milk.
It is used in the treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH).
It introduces a reduced risk of urine retention (AUR) and surgery in patients with moderate to severe symptoms of BPH.
It reduces the levels of dihydrotestosterone (DHT) by inhibiting the isoenzymes type 1 and type 2 of 5-alpha reductase, which are responsible for the conversion of testosterone to DHT, and like other inhibitors of 5-alpha reductase, can reduce hair loss and induce growth in patients with a male pattern of hair loss (male androgenic alopecia).

Dosage
Orally, usually at a dose of 0.5 mg/day.

Side effects
DUTASTERIDE has been reported to affect semen characteristics (reduced sperm count) of healthy men. The possibility of male fertility being reduced cannot be excluded.
Among the most frequent side effects are impotence, alteration (decrease) of the libido, disorders in the ejaculation, disorders of the breast, allergic reactions (among which include rash, pruritus, urticaria, localized edema and angioedema), state of depressed mood, alopecia (mainly loss of body hair), hypertrichosis, and pain and testicular inflammation.

Contraindications
Women, children and adolescents.
Patients with hypersensitivity to DUTASTERIDE or other 5-alpha reductase inhibitors.
Patients with severe hepatic insufficiency.

Precautions
Before starting treatment, a digital rectal examination should be performed, as well as other methods of evaluating prostate cancer or other diseases that may cause the same symptoms as BPH.
Care should be taken in the administration in patients with mild to moderate hepatic impairment.

Interactions
The long-term combination of DUTASTERIDE with drugs that are potent inhibitors of the CYP3A4 enzyme (eg., ritonavir, indinavir, nefazodone, itraconazole, or ketoconazole given orally) may increase serum DUTASTERIDE concentrations.