METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

002493-TDS-ENG-2025

FINASTERIDA (EUR. PH.)		
DESCRIPTION DCI: finasteride	DESCRIPTION DOE: FINASTERIDA	
CAS Nº: 98319-26-7	EC Nº: 620-534-3	AEMPS CODE: 2624A
MOL. WEIGHT: 372,55	MOL. FORMULA: C23H36N2O2	ARTICLE CODE: 002493

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Practically insoluble in water, freely soluble in ethanol and in methylene chloride
Identification	Complies
Specific optical rotation	+12.0 / +14.0
Related substances	
Impurity A	=< 0.3 %
Impurity C	=< 0.3 %
Individual impurities	=< 0.10 %
Total of impurities	=< 0.5 %
Loss on drying	=< 0.5 %
Assay	98.0 - 102.0 %

COMPLIES WITH

European Pharmacopeia 11.0

STORAGE

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

REMARKS

It shows polymorphism.

Finasteride 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.

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
Finasteride is an analogue of testosterone that blocks the conversion of testosterone to dihydrotestosterone, the main and most potent androgen in the body, by inhibiting 5-alpha-reductase. Administered orally reduces benign prostatic hyperplasia, and is currently also used in the treatment of androgenic alopecia and topical and oral acne. It is absorbed after oral administration, reaching the maximum serum concentration after 1 - 2 h. The degree of binding to plasma proteins is 90%. It is metabolized in the liver, being eliminated mostly with faeces and urine. Its elimination half-life is 6 h (8 h in patients older than 70 years). It is formulated in capsules, ointments, and lotions.

Dosage
Topical route: the dose is not very well determined, but it is usually at 0.05 - 0.1%.
Oral route: dose of 1 mg / day in the treatment of androgenic alopecia, 5 mg / day in the treatment of benign prostatic

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hyperplasia.

Side effects
The most frequent adverse effects are the decrease of the libido, impotence, disorders of the ejaculation, and reduction of the volume of semen. Can be produced mastalgia and gynecomastia. Cases of hypersensitivity (such as swelling of the lips and face), itching, hives, and rash, and testicular pain have been reported.

Contraindications
Patients with allergy to the active substance. Women who are or may be pregnant. Children.

Precautions
A special clinical control should be performed in patients with renal insufficiency and liver failure. It should be administered with caution in men with obstructive uropathy. The patient should be reminded of the advisability of avoiding sexual intercourse without mechanical protection, given the hypothetical risk of inducing fetal malformations.