METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

TECHNICAL DATA SHEET

890-TDS-ENG-2025

PRASTERONA (DEHIDROEPIANDROSTERONA - DHEA) (FRENCH PH.)		
DESCRIPTION DCI: prasterone	DESCRIPTION DOE: PRASTERONA	
CAS Nº: 53-43-0	EC Nº: 200-175-5	AEMPS CODE: 2199A
MOL. WEIGHT: 288,42	MOL. FORMULA: C19H28O2	ARTICLE CODE: 890

ATTRIBUTES	SHOULD BE
Appearance	White or almost white crystalline powder
Solubility	Practically insoluble in water, soluble in 96% ethanol and in methylene chloride
Identification B	Complies
Specific rotation power	+11.0 / +14.0
Related substances	
Impurity A	=< 0.10 %
Impurity B	=< 0.10 %
Impurity D	=< 0.10 %
Impurity E	=< 0.10 %
Impurity F	=< 0.08 %
Impurity C	=< 0.02 %
Any other impurity	=< 0.10 %
Total impurities	=< 0.50 %
Hydroxilamine	=< 5 ppm
Water	=< 1.0 %
Sulfated ash	=< 0.1 %
Assay	97.5 - 102.0 %

COMPLIES WITH

French Pharmacopoeia 2025

STORAGE

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

REMARKS

Prasterone **VEGETAL ORIGIN** is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.

Description
PRASTERONE or DEHYDROEPIANDROSTERONE (DHEA) is the steroid hormone, produced by the adrenal glands, more abundant in humans.

DHEA is not present in the body until about 7-10 years of age, and its production increases to 25 years. From this age DHEA

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decreases gradually until reaching values of 10% with respect to the amount present in youth.

Actions
Significantly improves the physical and mental state, both in men and women of advanced age, with no side effects. This is possibly one of the most novel actions of this hormone, since it improves the quality of life in the last third of it.

It is an intermediary of the synthesis of sex hormones (testosterone and estrogens).

It is an anticancer agent: In spontaneous and induced colon adenocarcinoma (dose of 25-50 µg/L).
Preventive action in breast cancer, alone or in conjunction with the administration of N- (4-hydroxyphenyl) retinamide (4-HPR). It decreases the multiplicity of cancer if it is administered in the initial phase and decreases the incidence of the cancer process when it is administered during the promotion phase.

Due to the potentiation of the immune system, DHEA has a protective effect against certain viral infections, is an in vitro inhibitor of the replication of the human immunodeficiency virus type 1 (HIV-1) and reduces the incidence of cryptosporidiosis in animals. immunosuppressed
It has been proven that the administration of a DHEA supplement corrects immunodeficiency in old animals.

Use as an antiobesity agent since it promotes the hepatic oxidation of glucose and reduces glycogenesis. DHEA, in combination with a diet low in calories and rich in fiber, promotes the loss of excess weight (studies have been done in animals and humans).

Due to the protection against osteoporosis and cardiac problems, the effect of DHEA in postmenopausal women has been studied, concluding that it can be used as steroidal substitution therapy.

Rejuvenates the skin
Increases lividness