



GYNECOLOGY - ONCOLOGY

Cyproterone acetate 50mg

Mechanism of action

- Anti-androgen action by blocking androgen receptors
- Progestogenic activity which exerts a negative feedback effect on hypothalamic receptors, leading to a reduction in gonadotrophin release and hence to diminished production of testicular androgens

- In prostatic cancer: direct anti-androgen action on the tumour and its metastases

May be used alone or in conjunction with surgery or gonadorelin analogues

Therapeutic indications

- Prostatic cancer
- Control of libido in severe hypersexuality and/or sexual deviation male
- Female hirsutism

Posology and method of administration

- Prostatic cancer: 200-300mg per day (without interruption)
- Control of libido in severe hypersexuality and/or sexual deviation male: 200mg per day, after the morning and evening meals
- Female hirsutism (should be associated with estrogen):

2 possible therapeutic schemes:

- 100mg per day, 10 days a month (from the 1st day to the 10th day of the menstrual cycle); when combined with an estrogen

- 50mg per day, 20 days a month (from the 1st day to the 20th day of the menstrual cycle); when combined with an estrogen

cyproterone acetate fixed association

Advantages of this progestogen

- Contraceptive action (in addition to the therapeutic indications linked to its anti-androgenic action)
- Very efficient on all androgen-dependent conditions

Pharmaceutical form

Tablets

White, round, scored on one side and embossed "50" on the reverse side tablet

Composition

Active substance

Cyproterone acetate: 50 mg for one tablet

Presentations

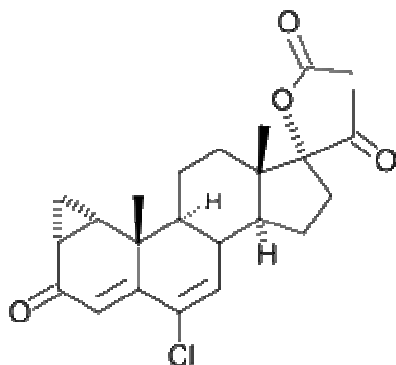
50mg: carton box containing blisters of 10 or 28 tablets

100mg: carton box containing blisters of 10 or 12 tablets



Pharmacopeial quality

Active substance: cyproterone acetate



- Synthetic
- Manufactured in Europe (GMP approved)
- E.P. compliant

Finished product

- Manufactured in Europe (dedicated plant for hormonal products, GMP approved)

Pharmacodynamic properties

Pharmacotherapeutic group/ATC code

G Genito urinary system and sex hormones

G03 Sex hormones and modulators of the genital system

G03H Antiandrogens

G03HA Antiandrogens, plain

G03HA01 Cyproterone