

Andriol

capsules for oral use

Composition

Andriol contains testosterone undecanoate (TU), a fatty acid ester of the natural hormone testosterone.

Each capsule contains 40 mg TU dissolved in oleic acid. The capsule bears the code 'ORG' on one side and the code 'DV 3' on the reverse side.

Characteristics

Pharmacodynamic properties

Testosterone is the principal endogenous hormone essential for normal growth and development of the male sex organs and male secondary sex characteristics. During adult life testosterone is essential for the functioning of the testes and accessory structures, and for the maintenance of libido, sense of well-being, erectile potency, prostate and seminal vesicle function.

Treatment of hypogonadal men with Andriol results in a clinically significant rise of plasma concentrations of testosterone, dihydrotestosterone and androstenedione, as well as a decrease of SHBG (sex hormone binding globulin). In males with primary (hypergonadotropic) hypogonadism treatment with Andriol results in a normalization of gonadotropin levels.

Pharmacokinetic properties

Following oral administration, testosterone undecanoate is co-absorbed with the oleic acid from the intestine into the lymphatic system, thus circumventing the first-pass inactivation by the liver. During absorption testosterone undecanoate is partly reduced to dihydrotestosterone undecanoate. From the lymphatic system it is released into the plasma. In plasma and tissues both testosterone undecanoate and dihydrotestosterone undecanoate are hydrolyzed to yield the natural male androgens testosterone and dihydrotestosterone. Single administration of 80–160 mg Andriol leads to a clinically significant increase of total plasma testosterone with peak-levels of approximately 40 nmol/l (C_{max}), reached approximately 4–5 h (t_{max}) after administration. Plasma testosterone levels remain elevated for at least 8 hours. Testosterone and dihydrotestosterone are metabolized via the normal pathways. Excretion mainly takes place via the urine as conjugates of etiocholanolone and androsterone.

Indications

In males: testosterone replacement therapy for primary or secondary hypogonadal disorders, for example:

- after castration,
- eunuchoidism,
- hypopituitarism,
- endocrine impotence,
- certain types of infertility due to spermatogenic disorders,
- male climacteric symptoms such as decreased libido and decreased feeling of general well-being and fitness.

In female-to-male transsexuals:

- masculinization.

Moreover, in men testosterone therapy may be indicated in osteoporosis caused by androgen deficiency.

Dosage and administration

In general, dosage should be adjusted according to the response of the individual patient.

Usually, an initial dosage of 120–160 mg

TU daily for 2–3 weeks is adequate, followed by a maintenance dosage of 40–120 mg TU daily.

Andriol should be taken after meals, with some fluid and swallowed whole without chewing. It is preferable that half of the daily dose be taken in the morning and the other half in the evening. If an odd number of capsules is taken, the larger dose should be taken in the morning.

Contraindications

- Known or suspected prostatic carcinoma or breast carcinoma in the male
- Pregnancy
- Breast-feeding

Warnings and precautions

- Androgens should be used with caution in (pre)pubertal boys to avoid premature epiphyseal closure or precocious sexual development. Skeletal maturation should be monitored regularly.
- Patients with latent or overt cardiac failure, renal dysfunction, hypertension, epilepsy or migraine (or a history of these conditions) should be kept under close medical supervision, since aggravation or recurrence may occasionally be induced.
- Androgens should be used with caution in men suffering from benign prostatic hypertrophy.
- If androgen-associated adverse reactions occur, Andriol treatment should be interrupted and, after disappearance of the symptoms, be resumed at a lower dosage.
- The use of steroids may influence the results of certain laboratory tests.
- For the information of sportsmen: Andriol contains an ingredient that may give a positive reaction in a doping test.

Adverse reactions

The following adverse reactions have been associated with androgen therapy in general:

- in prepubertal boys:
 - precocious sexual development,
 - increased frequency of erections, phallic enlargement and premature epiphyseal closure;
- in men:
 - priapism and other signs of excessive sexual stimulation, oligospermia and decreased ejaculatory volume;
- in all patients:
 - water and sodium retention.

Interactions

Enzyme-inducing agents may exert increasing or decreasing effects on testosterone levels. Therefore adjustment of the dose of Andriol may be required.

Pregnancy and lactation

Andriol must not be used during pregnancy or lactation.

Effects on ability to drive and use machines

As far as known Andriol has no adverse influence on alertness and concentration.

Overdosage

The acute oral toxicity of TU is very low. High dosages of Andriol may cause gastrointestinal complaints due to the solvent (oleic acid) contained in the capsule. Treatment may consist of emptying the stomach and supportive measures.

In correspondence please quote packing number.