

InduJect™ - 250

GENERIC NAME:
InduJect™-250 Injection

CHEMICAL NAME:
17 β -hydroxy-4-androsten-3-one

IUPAC NAME:
(8S,9S,10R,13S,14S,17S)-17hydroxy-10,13-dimethyl -1,2,6,7,8,9,11,
12,14,15,16,17-dodecahydrocyclopenta[a]phenanthren-3-one.

MOLECULAR FORMULA:
C₁₉H₂₈O₂

MOLECULAR WEIGHT:
288.429 g/mol.

DOSAGE FORM:
250mg/1ml injection.

COMPOSITION:
Induject™ is a blend of different esterated testosterone (4 of them):

Testosterone propionate - 30 mg,

Testosterone phenylpropionate - 60 mg,

Testosterone isocaproate - 60mg,

Testosterone decanoate -100 mg.

(equivalent to 176mg of testosterone).

Other ingredients in the injection are: Ethyl Oleate and Benzyl alcohol.

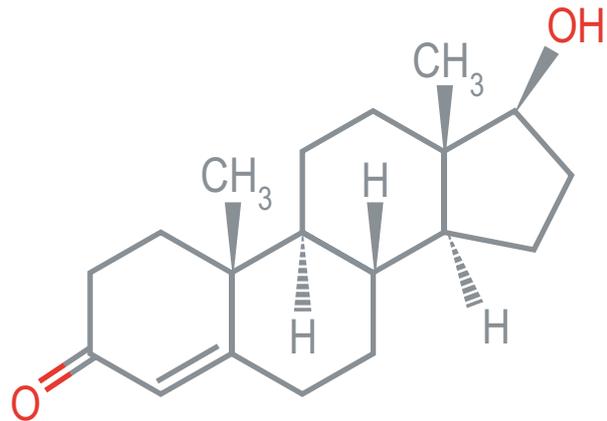
PHARMACOLOGICAL CLASSIFICATION:
Androgenic Hormone.

MECHANISM OF ACTION:

Induject™ injection contains testosterone esters. These are derivatives of the naturally occurring male hormone testosterone. They are converted in the body to testosterone.

Testosterone is produced by the testicles and is the main hormone essential for normal growth and development of the male sex organs and male sexual characteristics.

The natural production of testosterone is controlled by gonadotrophins, which are released from the pituitary gland in the brain. During adult life, testosterone is essential for the functioning of the testes and accessory structures, the maintenance of libido, sense of well being, erectile potency and the functioning of the prostate gland. It also has functions in the skin, muscles, skeleton, kidney, liver, bonemarrow and central nervous system.



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 $C_{19}H_{28}O_2$

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MECHANISM OF ACTION: (Contd.)

Low levels of testosterone can cause decreased sex drive, impotence, infertility due to decreased sperm production, decreased mental and physical activity, fatigue and weakening of bones. Testosterone is given as replacement therapy when natural testosterone levels fall too low, causing symptoms such as those above.

PHARMACOKINETIC PROPERTIES:

Induject™ contains four esters of testosterone with different duration of action. The esters are hydrolyzed into natural hormone testosterone as they enter the circulation system. A single dose of Induject™ leads to increased plasma testosterone levels after administration. The levels of plasma testosterone returns to lower limit of the normal range in 21 days approx.

INDICATIONS:

- Replacement therapy of low testosterone levels in men.
- Male menopause symptoms such as decreased sex drive.
- Prevention and treatment of osteoporosis in men with low testosterone levels.

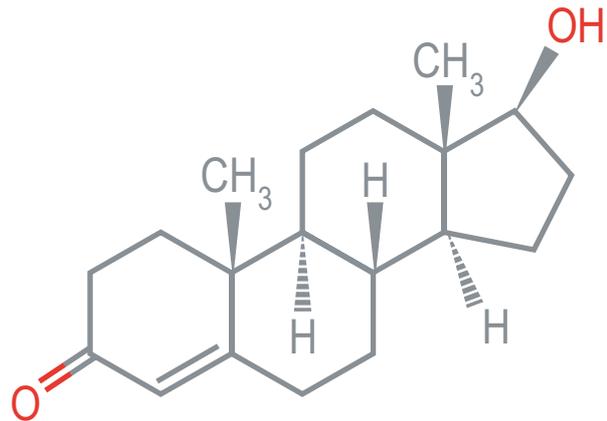
SIDE EFFECTS AND SPECIAL PRECAUTIONS:

SIDE EFFECTS:

The following are some of the side effects that are known to be associated with Induject™. High blood pressure (hypertension), breast pain, enlargement of the breasts, swelling caused by fluid retention (oedema), hair loss, acne, depression, hostility, nervousness, prostate problems, prolonged painful erection of the penis, decreased sperm count, increased levels of red blood cells and hemoglobin in the blood, jaundice, liver tumors, increased sexual desire, premature closure of the



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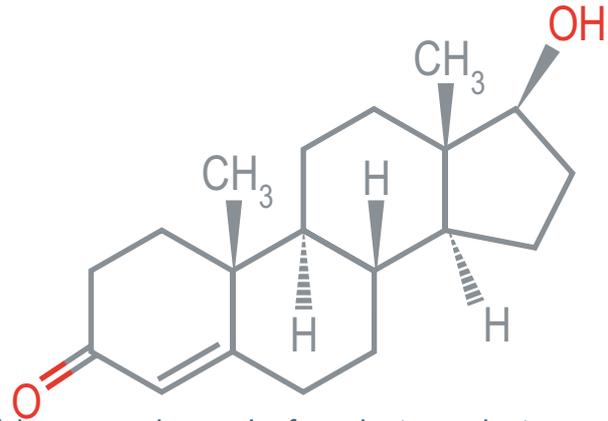
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ends of bones, causing stunted growth when used in young boys. In female-to-male transsexuals additional possible side effects are: weight gain, loss of bone mineral density (osteoporosis), increased risk of endometrial and ovarian cancer .Ongoing monitoring and supervision is required to detect signs of osteoporosis, endometrial and ovarian cancer.

SPECIAL PRECAUTIONS:

Androgens should be used with caution in people with Renal / Hepatic impairment, epilepsy, migraine, cancer of the bone, diabetes. If you are a female-to-male transsexual, you should have special assessments, including psychiatric assessment, before treatment is started.

CONTRA-INDICATIONS:

Prostatic carcinoma, male breast cancer, cardiac failure, pregnancy and lactation. Please inform your doctor or pharmacist if you have previously experienced such an allergy. If you feel you have experienced an allergic reaction, stop using this medicine and inform your doctor or pharmacist immediately.

WARNING!

- Consult a doctor, if you experience symptoms such as frequent or persistent erections, irritability, nervousness or weight gain after starting treatment with this medicine, as these suggest your testosterone levels are too high and your dose may need adjusting.
- Regular blood tests to monitor red blood cells, liver function and prostate specific antigen (PSA) levels.
- The use of steroids may influence the results of certain laboratory tests.



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DRUG INTERACTIONS:

- Induject™ may increase the anti-blood-clotting effects of anticoagulants such as warfarin, nicoumalone and phenindione.
- If testosterone is used in combination with corticosteroids such as dexamethasone, there may be a greater chance of fluid retention and oedema. This combination of medicines should be used with caution in people with heart, liver or kidney disease.
- Enzyme-inducing agents may exert increasing or decreasing effects on testosterone levels.

PRESENTATION:

1 ampoules of 1ml (250mg/ml) in a blister pack. Blister packing of 50 ampoules in one carton.

DOSAGE AND DIRECTIONS FOR USE

Induject™ injection is called a depot injection. The injection is usually given once every two to three weeks, though the frequency will depend on your individual testosterone levels. Induject™ is injected intramuscularly.

● ADULTS (MALE):

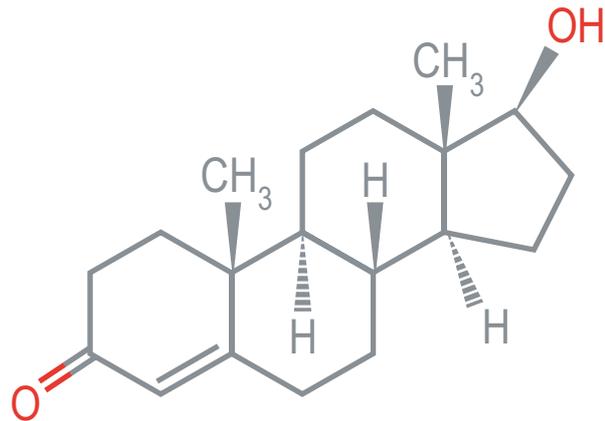
For Induject™ usually one injection of 1ml every three weeks is given.

● ADULTS (FEMALE-TO-MALE TRANSSEXUALS):

Doses may vary from one injection of 1ml Induject™ every two weeks to one injection of 1ml Induject™ every four weeks, depending on the individual.



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STORAGE :

- Do not store above 25 °C. Do not refrigerate or freeze.
- Keep the ampoules in the outer carton to protect from light.
- Induject™ should be kept out of reach and sight of children.

MARKETED BY

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