

# Nandrolin® 200mg/2ml

## GENERIC NAME

Nandrolone Decanoate

## CHEMICAL NAME

17 beta-hydroxy-19-norandrost-4-en-3-one 17-decanoate

## MOLECULE STRUCTURE

C<sub>28</sub>H<sub>44</sub>O<sub>3</sub>

## MOLECULE WEIGHT

446.669

PROPRIETARY NAME: Nandrolin®

DOSAGE FORM: 200mg/2ml injection

## COMPOSITION

Nandrolin® contains 200 mg Nandrolone decanoate B.P in 2 ml of Ethyl Oleate B.P solvent.

## PHARMACOLOGICAL CLASSIFICATION

Anabolic Steroids

## PHARMACOLOGICAL ACTION

Nandrolin® has both androgenic and anabolic properties when administered parentally. Nandrolone decanoate is gradually released from the intramuscular depot and subsequently hydrolyzed into Nandrolone.

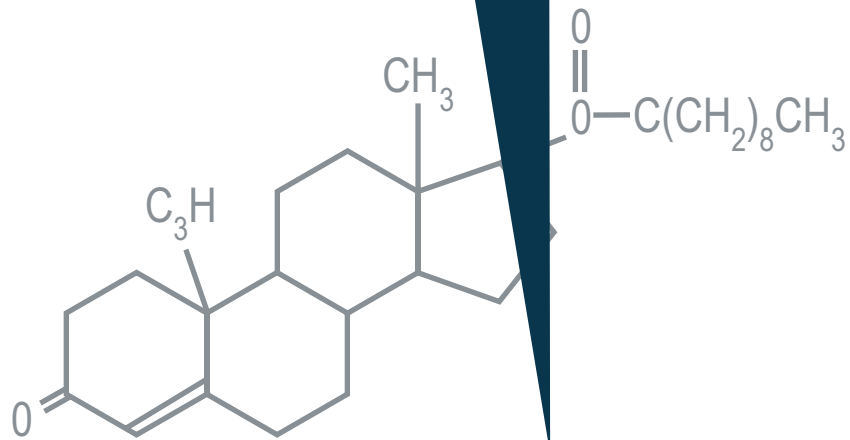
## INDICATIONS

- 1) Nandrolin is indicated in the treatment of anemia associated with renal insufficiency.
- 2) Certain cases of disseminated breast cancer in post-menopausal women and women without ovaries.
- 3) Osteoporosis due to androgen deficiency in hypogonadal males.

## CONTRA-INDICATIONS

- Contraindicated in infant, pregnancy & lactating mothers.
- Carcinoma of prostate and carcinoma of male breast.
- Contraindicated in nephrosis or the nephrotic phase of nephritis, cardiac and renal failure, hyper-calcaemia, oedema, jaundice, liver disease with impaired bilirubin excretion, testicular and hepatic carcinoma.

*Nandrolone Decanoate is not intended for use in female patients other than those with disseminated breast cancer.*



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## DOSAGE AND DIRECTIONS FOR USE

Nandrolin® injections should be administered intramuscularly, preferably deep into the gluteal muscle. When using Nandrolone decanoate injections, an adequate iron intake is required for maximum response. If any solid matters separate out, it should be redissolved by warming before use.

## ADULTS

Females: Intramuscular, 50 to 100 mg given every one to four week.

Males: Intramuscular, 50 to 200 mg given every one to four week.

Note: When given at three to four week intervals, therapy may be continued for up to 12 weeks. If necessary, cycle may be repeated if second course is preceded by a four-week rest period.

## Children

Children up to 2 years of age : Dosage might be determined by the physician.

Children 2 to 13 years of age : Intramuscular, 25 to 50 mg every three to four weeks.

## SIDE-EFFECTS

Oedema, cholestatic jaundice, hepatic carcinoma. Gynaecomastia. Precocious puberty & shortening of stature due to early closure of epiphysis. Rashes, cramps, dyspepsia. Virilization which appears in sensitive women as hoarseness, acne, hirsutism, and increased libido and menstrual irregularities.

## PRECAUTIONS

Patients with the following conditions should be monitored:

- In cardiac failure, renal dysfunction, hypertension, epilepsy or migraine (or a history of these conditions), since anabolic steroids may induce salt and fluid retention.
- Diabetes : Anabolic steroids may improve the glucose tolerance and decrease the need for insulin or other antidiabetic drugs.
- Incomplete statural growth : Anabolic steroids in high dosages may accelerate epiphyseal closure.
- Skeletal metastases : Anabolic steroids may induce hypercalcemia and hypercalciuria in these patients.
- Liver dysfunction.
- If signs of virilization develop, treatment should be discontinued.



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## DRUG –INTERACTIONS

- Potentiates corticosteroids.
- Potentiates oral anticoagulants thereby enhancing bleeding tendency.
- Liver-enzyme-inducing agents may reduce the effects of Nandrobolin® by enhancing its metabolism in the liver.
- Reducing efficacy of cyclophosphamide in advanced breast cancer.

## OVERDOSAGE

Overdoses are not frequent as physician or other expert administers it. Acute intramuscular toxicity of nandrolone is very low.

## STORAGE CONDITIONS

Not to be refrigerated.

Store in a cool dry place below 25 °C.

Protect from light.

Keep out of reach of children.

## PACKAGING

Container contains 1 vial of 2ml Nandrobolin with clear, yellowish oily solution. Each vial contains 200mg Nandrolone decanoate.

## MARKETED BY

Alpha-Pharma Healthcare India Pvt. Ltd.

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Mumbai 400072

India

## DATE OF PUBLICATION OF THIS PACKAGE INSERT

20th of April 2007