Nandurabolin 25 mg & 50 mg / ml

This product contains benzyl alcohol ,which may be fatal in neonates and infants.

1-Name of the medicinal product : Nandurabolin 25 mg &50mg/ml

2-Qualitative and quantitative composition

Each ml of Nandurabolin 25 contains 25mg nandrolone decanoate.
Each ml of Nandurabolin 50 contains 50mg nandrolone decanoate.

3-Pharmaceutical form: Solution for injection.

4- Clinical particulars

4.1Therapeutic indications:

For use in osteoporosis in post-menopausal women.
Established osteoporosis should have been diagnosed by the following parameters:
i) Crush or wedge fractures of the vertebrae.
ii) Other osteoporotic fractures.
iii) Established reduction in bone mineral content as measured by accepted BMC measurements.

4.2 Posology and method of administration:

•Dosage:
-Post-menopausal women : 50 mg every three weeks.
The duration of treatment depends on the clinical response and the possible occurrence of side-effects.
We would recommend that the effectiveness of therapy be monitored with the appropriate methods for osteoporosis on a 6-12 monthly basis.
-Children: There are no recommendations for use in children.
•Administration: Deep intramuscular injection.

4.3 Contraindications:

-Pregnancy , Nursing mothers &Pediatric use.
-Do not administer injections preserved with benzyl alcohol to neonates , infants below 13 years, pregnant women or nursing mothers. Benzyl alcohol has been associated with serious adverse events& death, particularly in pediatric patients (it may cause Gasping syndrome). Injections preservative free should be used in these populations.
-Porphyria , allergies to any of the components and known or suspected carcinoma of prostate or mammary carcinoma in the male.

4.4 Special warnings and precautions for use:

-If signs of virilisation develop, discontinuation of the treatment should be considered.
-This product contains benzyl alcohol which is potentially toxic when administered locally to neural tissue.
-This product is contraindicated for use in premature infants because the formulation contains benzyl alcohol.
-Patients, especially the elderly, with the following conditions should be monitored:
•latent or overt cardiac failure, renal dysfunction, hypertension, epilepsy or migraine (or a history of these conditions), since anabolic steroids may occasionally induce sodium and water retention.
•Incomplete statural growth, since anabolic steroids in high dosages may accelerate epiphyseal closure; skeletal metastases, since anabolic steroids may induce hypercalcaemia and hypercalciuria in these patients.
•Liver dysfunction - caution should be used in patients with severe hepatic impairment and Nandurabolin 25 mg & 50mg/ml should only be used if the benefits outweigh the risks.
•Diabetes mellitus.
-Nandurabolin 25 mg& 50mg/ml contains Arachis oil (peanut oil) and should not be taken / applied by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with Soya allergy should also avoid Nandurabolin 25 mg &50mg/ml.
-The use of anabolic steroids to enhance athletic ability may carry severe risks to the user's health and should be discouraged.

4.5 Interactions with other medicinal products and other forms of interactions

Anabolic steroids may improve glucose tolerance and decrease the need for insulin or other antidiabetic drugs in diabetics.

4.6 Pregnancy and lactation: Nandurabolin is contra-indicated during pregnancy and lactation because of possible masculinisation of the foetus.

4.7 Effects on ability to drive and use machines : None known

4.8 Undesirable effects:

Nandurabolin at the recommended dosages is unlikely to produce virilising effects. High dosages, prolonged treatment and/or too frequent administration may cause:
-Virilisation which appears in sensitive women as hoarseness, acne, hirsutism and increase of libido;in prepubertal boys as an increased frequency of erections and phallic enlargement, and in girls as an increase of pubic hair and clitoral hypertrophy. Hoarseness may be the first symptom of vocal change which may end in long-lasting, sometimes irreversible deepening of the voice.
-Amenorrhoea and inhibition of spermatogenesis.
-Premature epiphyseal closure.
-Sodium and water retention.
Abnormal liver function tests have been reported in patients treated with (high doses) of Nandurabolin.
Liver tumours have been reported occasionally on prolonged treatment with orally active C17-alpha alkylated anabolic steroids. A relationship between liver tumours and non-C17-alkylated injectable steroids, such as nandrolone esters, appears to be highly unlikely, but cannot be absolutely excluded.

4.9 Overdose:

The acute toxicity of nandrolone decanoate in animals is very low. There are no reports of acute overdosage with Nandurabolin in the human.

5- Pharmacological properties

5.1 Pharmacodynamic properties:

-Nandrolone is chemically related to testosterone and shows enhanced anabolic and a reduced androgenic activity.
-In humans Nandurabolin has been shown to positively influence calcium metabolism and to increase bone mass in osteoporosis.
-Androgenic effects (e.g. virilisation) are relatively uncommon at the recommended dosages. Nandrolone lacks the C17 alpha-alkyl group which is associated with the occurrence of liver dysfunction and cholestasis.

5.2 Pharmacokinetic properties:

-Nandrolone decanoate is slowly released from the injection site into the blood with a half-life of 6 days.
The ester is rapidly hydrolysed to nandrolone in the blood with a half-life of one hour or less. The half-life for the combined process of hydrolysis of nandrolone decanoate and of distribution and elimination of nandrolone is 4.3 hours.
-Nandrolone is metabolised by the liver. 19-norandrosterone, 19-noretiocholanolone and 19-norepiandrosterone have been identified as metabolites in the urine. It is not known whether these metabolites display a pharmacological action.

5.3 Preclinical safety data: Not applicable.

6- Pharmaceutical particulars

6.1 List of excipients : Benzyl alcohol, Arachis oil

6.2 Incompatibilities: None known

6.3 Shelf life :1 ml ampoule 24 months.

6.4 Special precautions for storage:

Do not store above 30°C
Do not refrigerate or freeze.
Keep in the container in the outer carton.

6.5 Nature and contents of container: 1 x 1ml ampoules

Manufactured by Chemical Industrial Development Co. (CID)
for El - Nile Company for Pharmaceuticals and Chemical Industries
Cairo - A.R.E R.C.C. 115668

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor s prescription, the method of use and the instructions of the pharmacist who sells the medicament.
- The doctor and the pharmacist are experts in medicine its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

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50 mg : 231224