STANOZOLOL®

Stanozolol USP29, Ph.Eur.5.5, Supermircronized grade
Suspension Injectable
Formula: C_{18}H_{20}N_{2}O (CAS-10161-34-9)
Molecular Weight: 344.592 g/mol
Active life: 8 hours
Detection time: 9 weeks
Anabolic/Androgenic ratio: 320/30

DESCRIPTION:
Stanozolol®, brand of Stanozolol suspension injection, is an anabolic steroid, a synthetic derivative of testosterone. Each ml contains 50, 75 and 100 mg Stanozolol USP29. Ph.Eur.5.5, supermircronized grade. It is designated chemically as 17-methyl-27R- 

CLINICAL PHARMACOLOGY:
Anabolic steroids are synthetic derivatives of testosterone. Certain clinical effects and adverse reactions demonstrate the anabolic properties of this class of drugs. Complete dissociation of anabolic and androgenic effects has not been achieved. The actions of anabolic steroids are therefore similar to those of male sex hormones with the possibility of causing various disturbances of growth and sexual development if given to young children. They suppress the gonadotropic functions of the pituitary and may exert a direct effect upon the tests.

Stanozolol® has been found to increase low-density lipoproteins and decrease high-density lipoproteins. These changes are not associated with any increase in total cholesterol, triglyceride levels and revert to normal on discontinuation of treatment.

Hereditary angioedema (HAE) is an autosomal dominant disorder caused by a deficit or nonfunctional C1 esterase inhibitor (C1 INH) and clinically characterised by recurrent attacks of swelling of the face, extremities, genitalia, bowel wall, and upper respiratory tract. In small scale clinical studies, Stanozolol® was effective in controlling the frequency and severity of attacks of angioedema and in increasing serum levels of C1 INH and C4. Stanozolol® is not effective in stopping HAE attacks while they are underway. The effect of Stanozolol® on increasing serum levels of C1 INH and C4 may be related to an increase in protein anabolism.

INDICATIONS AND USAGE:
- General deterioration status, different origin slimes, anorexia not responding to treatment, convalescence, chronic and weakening disease.
- Nephrotic and athermic patients with immunological and rheumatoid arthritis, for counteracting catabolic effects produced by corticosteroids.
- As coagulant in the treatment of decubitus ulcers, bone fractures of slow recovery, osteomyelitis, extensive burns before and after a surgical operation.
- In pancreatitis, in growth failure in length and weight, sonographic hypoproteinemia, diastrophy and immaturity.

Stanozolol® is a water-soluble suspension formulated for a prolonged absorption and with no local irritative effects. Its use is preferable provided that the doctor considers separate in time parenteral administrations more safe or more convenient than oral daily administration. Shake the vial before use.

A diet rich and equilibrated is convenient when the product is being administered.

CONTRAINDICATIONS:
The use of Stanozolol® is contraindicated in the following:
1. Cancer of the prostate or breast in male patients.
2. Cancer of the breast in some females.
3. Nephrosis or the nephrotic phase of nephritis.
4. Stanozolol® can cause fetal deformities when administrated to a pregnant woman.

Stanozolol® is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

5. Hypersensitivity to stanozolol,

WARNINGS:
Anabolic steroids have the potential capacity of generating masculinizing effects, which can appear in the girls. If this happens, the treatment must be strictly controlled by the doctor. Long term treatment to promote growth must be interrupted when the skeletal age (to be controlled by radiology every 6 months) approaches the chronological age.

It is informed to sportmen that this product contains a component that can give a positive analytical result in doping control.

LIVER CELL TUMORS ARE REPORTED. MOST OFTEN THESE TUMORS ARE BENIGN AND ANDROGEN DEPENDENT, BUT FATAL MALIGANANT TUMORS HAVE BEEN REPORTED. WITHDRAWAL OF DRUG OFTEN RESULTS IN REVERSION OR CESSATION OF PROGRESSION OF THE TUMOR. HOWEVER, HEPATIC TUMORS ASSOCIATED WITH ANABOLIC OR ANABOLIC STEROIDS ARE MUCH MORE VASCULAR THAN OTHER HEPATIC TUMORS AND MAY BE SILENT UNTIL LIFE-THREATENING INTRA-ABDOMINAL HEMORRHAGE DEVELOPS.
PELLOUS HEPATIS, A CONDITION IS ALSO REPORTED IN WHICH LIVER AND SPLENOMEGLY IS REPLACED WITH BLOOD-FILLED CYSTS, HAS BEEN REPORTED IN PATIENTS RECEIVING ANDROGENIC ANABOLIC STEROID THERAPY. THESE CYSTS ARE SOMETIMES ASSOCIATED WITH MINIMAL HEPATIC DYSFUNCTION, BUT AT OTHER TIMES THEY HAVE BEEN ASSOCIATED WITH LIVER FAILURE. THEY ARE OFTEN NOT RECOGNIZED UNTIL LIFE-THREATENING LIVER FAILURE OR INTRA-ABDOMINAL HEMORRHAGE DEVELOPS. WITHDRAWAL OF DRUG USUALLY RESULTS IN COMPLETE DISAPPEARANCE OF LESIONS.
HILUS LIVER CHANGES ARE KNOWN TO BE ASSOCIATED WITH INCREASED RISK OF ATHEROCELSIS ARE SEEN IN PATIENTS TREATED WITH ANABOLIC AND ANABOLIC STEROIDS. THESE CHANGES include DECREASED HIGH-DENSITY LIPROTEIN AND SOMETIMES INCREASED LOW-DENSITY LIPROTEIN. THE CHANGES MAY BE VERY MARKED AND COULD HAVE A SERIOUS IMPACT ON THE RISK OF ATHEROCELSIS AND CORONARY ARTERY DISEASE.

General: Women should be observed for signs of virilization (deepening of the voice, hirsutism, acne, and clitoromegaly). To prevent irreversible change, drug therapy must be discontinued, or the dosage significantly reduced when mild virilism is first detected. Such virilization is usual following anabolic anabolic steroid use at high doses. Some virilizing characteristics in females are irreversible even after prompt discontinuation of therapy and are not prevented by concomitant use of estrogens. Menstrual irregularities may also occur. The insulin or oral hypoglycemic dosage may need adjustment in diabetic patients who receive anabolic steroids.

Information for the Patient: The patient should be instructed to stop any of the following side effects of anabolics: Adults or Adolescent Males: Too frequent or persistent erections of the penis, appearance or aggravation of acne. Women: Hirsutism, acne, changes in menstrual periods, or more hair on the face. All Patients: Any nausea, vomiting, changes in skin color, or ankle swelling.

Laboratory Tests: Women with disseminated breast carcinoma should have frequent determination of urine and serum calcium levels during the course of anabolic anabolic steroid therapy (see WARNINGS). Because of the hepatotoxicity associated with the use of 17-alpha-alkylated anabolics, liver function should be monitored periodically.

Periodic (every 6 months) x-ray examinations of bone age should be made during treatment of prepubertal patients to determine the rate of bone maturation and the effects of anabolic anabolic steroid therapy on the epiphyseal centers. In common with other anabolic steroids, Stanozolol® has been reported to lower the level of high-density lipoproteins and raise the level of low-density lipoproteins. These changes usually revert to normal on discontinuation of treatment. Increased low-density lipoproteins and decreased high-density lipoproteins are common in older patients with coronary artery disease. Serum lipids and high-density lipoprotein cholesterol should be determined periodically.

Carcinogenesis, Mutagenesis, Impairment of Fertility:
Stanozolol has not been tested in laboratory animals for carcinogenic or mutagenic effects. No tumorigenic or cancer inducing properties of Stanozolol were seen in one-year toxicity studies in rats.

Stanozolol administered orally (intragastrically) to pregnant rats at dosages of 2.5 mg/kg/day to 20 mg/kg/day increased the anogenital distance in rat fetuses, indicative of a masculinizing effect. Stanozolol prevented pregnancy when given orally to rat from the 1st to the 21st day of gestation.

No teratogenic effects on congenital malformation were observed in offspring of rabbits given 0.5 mg/doy, 1.0 mg/doy, or 5.0 mg/doy of Stanozolol from the 8th through the 16th day of pregnancy, nor were there any adverse effects on the course of pregnancy at these dose levels.

Pregnancy: Category X See CONTRAINDICATIONS section.

Nursing Mothers: It is not known whether anabolic steroids are excreted in human milk. Many drugs are excreted in human milk and because of the potential for adverse reactions in nursing infants from Stanozolol®, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric use: Anabolic agents may accelerate epiphyseal maturation more rapidly than linear growth in children, and the effect may continue for 6 months after the drug has been stopped. Therefore, therapy should be monitored by x-ray studies at 6 month intervals in order to avoid the risk of compromising the adult height. The safety and efficacy of Stanozolol® in children with hereditary angioedema have not been established.

OVERDOSAGE:
Cholestatic hepatitis and jaundice occur with 17-alpha-alkylated anabolics at relatively low dose levels. Chloroquine overdose can also cause cholestatics. Disulfiram-like reactions have been rarely reported after high dose and prolonged therapy with Stanozolol®. If jaundice or other signs of hepatitis occur, the anabolic steroid should be discontinued. If liver function tests become abnormal, the patient should be monitored closely and the etiology determined. Generally, the anabolic steroid should be discontinued although in cases of mild abnormalities, the physician may elect to follow the patient cautiously and discontinue the drug if jaundice persists.

In patients with breast cancer, anabolic steroid therapy may cause hypercalcemia by stimulating osteolysis. In this case, the drug should be discontinued.

Glomerular filtration rate, or without congestive heart failure may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease.

Gynecomastia male patients treated with anabolic anabolic steroids may be at an increased risk for the development of prostatic hyperplasia and prostatic neoplasms.

Anabolic steroids have not been shown to enhance athletic ability.

At the therapeutically dosages, no acute toxicity should be expected.

DRUG INTERACTION:
Anabolic steroids may increase sensitivity to anticoagulants; therefore, dosage of an anticoagulant may have to be decreased in order to maintain the prothrombin time at the desired therapeutic level.

Drug/Laboratory Test Interferences: Therapy with anabolic anabolic steroids may decrease the levels of thyroxine-binding globulin resulting in decreased total T3 and T4 levels and increase resin uptake of T3 and T4. Free thyroid hormone levels remain unchanged and there is no clinical evidence of thyroid dysfunction. Anabolic steroids may cause an increase in prothrombin time.

ADVERSE REACTIONS:
Hepatic: Cholestasis and jaundice rarely, hepatic necrosis and death. Hepatocellular necrosis, cholestasis and peliosis hepatic have been reported in association with long-term anandionic-anabolic steroid therapy (see WARNINGS). Reversible changes in liver function tests also occur including increased bromsulphalein (BSP) retention and increases in serum bilirubin, glutamic oxaloacetic transaminase (SGOT) and alkaline phosphatase.

Gastrointestinal: Nausea, vomiting, diarrhea.

Larynx: Deepening of the voice in women.

Hair: Hirsutism and male pattern baldness in women.

Skin: Acne (especially in women and prepubertal boys).

Skeletal: Premature closure of epiphyses in children (see PRECAUTIONS, Pediatric use).

Fluid and Electrolytes: Edema, retention of serum electrolytes (sodium, chloride, potassium, phosphate, calcium).

Metabolic/Endocrine: Decreased glucose tolerance (see PRECAUTIONS), increased serum levels of low-density lipoproteins and decreased levels of high-density lipoproteins (see PRECAUTIONS, Laboratory Tests), increased creatinine and creatinine clearance, increased serum levels of creatinine phosphokinase (CPK).

Some virilizing changes in women are irreversible even after prompt discontinuance of therapy and are not prevented by concomitant use of estrogens (see PRECAUTIONS).

**PATIENT MONITORING:**

Lipid profile: Serum Cholesterol, HDL, LDL, TG.

Hemoglobin and Hematocrit.

Liver function test: Total protein, Albumin, Globulin, Total and direct bilirubin, AST, ALT and alkaline phosphatase, tumor marker for liver: AFP and CA19-9.

Prostatic specific antigen: PSA, Testosterone: total, free, and bioavailable.

Dihydrotestosterone & Estradiol

Male patients over 40 should undergo a digital rectal examination and evaluate PSA prior to androgen use. Periodic evaluations of the prostate should continue while on androgen therapy, especially in patients with difficulty in urination or with changes in voiding habits.

**DOSE AND ADMINISTRATION:**

The use of anabolic steroids may be associated with serious adverse reactions, many of which are dose related; therefore, patients should be placed on the lowest possible effective dose.

**Hereditary Angioedema:** The dosage requirements for continuous treatment of hereditary angioedema with Stanazolol® should be individualized on the basis of the clinical response of the patient.

Children: according to medical prescription.

For Body building: Adult male: suggested dose 50–100 mg per day intramuscular injection under care of physician; female: suggested dose 2.5–10 mg per day.

**HOW SUPPLIED:** Stanazolol® suspension Injection, Solution: Intramuscular

-50 mg/ml is supplied in 1 ml vial with red color flip cap and in multiple dose 10 ml vial with orange color flip cap

-75 mg/ml is supplied in multiple dose 10 ml vial with warm red color flip cap

-100 mg/ml is supplied in multiple dose 10 ml vial with yellow color flip cap

For shelf-life please refer to the imprint on the pack.

Shake the vial before its use.

Keep out of reach of children.

Should be at controlled room temperatures 15-30°C (59-86°F)

Do not freeze

Protect from sunlight

This drug has not been shown to be safe and effective for the enhancement of athletic performance!

**Manufactured and Distributed by:** LA Pharma S.r.l.

**Date of approval:** 15/2/2015