## **BOLDMAX®**

### **Boldenone Undecylenate**

Formula: C<sub>19</sub>H<sub>26</sub>O<sub>2</sub>

Molecular Weight (base): 286.4132 gm/mol Molecular Weight (ester): 186.2936 gm/mol

Active life: 15 days

Detection time: up to 5 months Anabolic/Androgenic ratio: 100:50

#### DESCRIPTION:

BoldMax sis a steroid compound that is described chemically as 1,4-androstadiene-3-one, 17b-ol.

BoldMax<sup>®</sup> is a 400 mg per ml of Boldenone Undecylenate, Miglyol 840, Ethyl oleate, Benzyl benzoate, Benzyl alcohol which is an oily solution for intramuscular injection. BoldMax<sup>®</sup> is designed to release Boldenone slowly from the injection site. BoldMax<sup>®</sup> is an anabolic steroid possessing anabolic properties with moderate androgenic activity. Anabolic and androgenic agents are widely used in the treatment of catabolic processes where accelerated strength and muscular development are indicated.

Boldenone Undecylenate has been used as an extremely powerful long acting anabolic agent which has a rapid onset of action. This is advantageous and is preferred over frequent oral dosing or even repeated injections in veterinary practice.

## **CLINICAL PHARMACOLOGY:**

Anabolic agents are related to the male sex hormones, but each varies in its anabolic and androgenic effect. Compounds such as methyltestosterone have anabolic activity, but with prolonged use, animals develop marked androgenic activity which makes these compounds unsuitable for prolonged.

Anabolic steroids suppress the gonadotropic functions of the pituitary and may exert a direct effect upon the testes. During exogenous administration of anabolic androgens, endogenous testosterone release is inhibited through inhibition of pituitary luteinizing hormone (LH). At large doses, spermatogenesis may be suppressed through feedback inhibition of pituitary follicle-stimulating hormone (FSH).

Pharmacological studies conducted in laboratory animals to evaluate the pharmacological activity characterized BoldMax<sup>®</sup> as having distinct anabolic properties together with a certain degree of androgenic activity. It does not have marked antigonadotropic properties nor does it produce any clear-cut effects on the endometrium, conditions that are commonly observed when similar substances are used.

In clinical trials, at the recommended dosage, BoldMax<sup>®</sup> had a marked anabolic effect in debilitated horses; appetite improved, vigor increased and improvement was noted in hair coat, musculature and strength. This would be expected with an anabolic agent such as BoldMax<sup>®</sup>, particularly where there had been marked tissue breakdown associated with disease, prolonged anorexia or overwork.

## INDICATIONS AND USAGE:

BoldMax<sup>®</sup> is indicated as an alternate or adjunctive therapy in patients for the promotion of weight gain following weight loss and/or muscular atrophy associated with extensive surgery, chronic infections, long term hospitalization, or severe trauma.

BoldMax should be considered only as an adjunctive therapy together with other androgenic medications.

Males: BoldMax<sup>®</sup> is indicated for increasing muscular mass, hardness and strength with low water retention and low estrogenic activity, as well as increasing the metabolic rate. Females: Women should take caution.

Horses: BoldMax<sup>®</sup> is recommended as an aid for treating debilitated horses when an improvement in weight, hair coat or general physical condition is desired. Debilitation often follows disease or may occur following overwork and overexertion. BoldMax<sup>®</sup> improves the general state of debilitated horses, thus aiding in correcting weight losses and improving appetite. It is not a substitute for a well-balanced diet. Optimal results can be expected only when good management and feeding practices are utilized.

For increased RBC: in severe anemic patients where first-line therapy is contraindicated. For promotion of increased appetite in patients; with appetite limited intake.

## CONTRAINDICATIONS:

BoldMax<sup>®</sup> is contradicted in men with the following:

- 1. Known hypersensitivity to any ingredients in this product.
- 2. Known or suspected carcinomas of the breast, testis, prostate gland, liver or kidney.
- Severe heart disease, liver disease, or kidney disease or with a history of epilepsy.
   Products containing androgens should not be used in women as they may cause virilization and fetal harm.

# WARNINGS:

LIVER CELL TUMORS ARE REPORTED. MOST OFTEN THESE TUMORS ARE BENIGN AND ANDROGEN DEPENDENT, BUT FATAL MALIGNANT TUMORS HAVE BEEN REPORTED. WITH DRAWAL OF DRUG OFTEN RESULTS IN REGRESSION OR CESSATION OF PROGRESSION OF THE TUMOR. HOWEVER, HEPATIC TUMORS ASSOCIATED WITH ANDROGENS OR ANABOLIC STEROIDS ARE MUCH MORE VASCULAR THAN OTHER HEPATIC TUMORS AND MAY BE SILENT UNTIL LIFE-THREATENING INTRA-ABDOMINAL HEMORRHAGE DEVELORS

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PELIOSIS HEPATIS, A CONDITION ARE ALSO REPORTED IN WHICH LIVER AND SOMETIMES SPLENIC TISSUE IS REPLACED WITH BLOOD-FILLED CYSTS, HAS BEEN REPORTED IN PATIENTS RECEVING ANDROGENIC ANABOLIC STEROID THERAPY. THESE CYSTS ARE SOMETIMES PRESENT 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 DISAPPERRANCE OF LESIONS.

DISAPPERRANCE OF LESIONS.
BLOOD LIPID CHANGES THAT ARE KNOWN TO BE ASSOCIATED WITH INCREASED RISK OF ATHEROSCLEROSIS ARE SEEN IN PATIENTS TREATED WITH ANDROGENS AND ANABOLIC STEROIDS. THESE CHANGES INCLUDE DECREASED HIGH-DENSITY LIPOPROTEIN AND SOMETIMES INCREASED LOW-DENSITY LIPOPROTEIN. THE CHANGES MAY BE VERY MARKED AND COULD HAVE A SERIOUS IMPACT ON THE RISK OF ATHEROSCLEROSIS AND CORONARY ARTERY DISEASE.

cardiovascular and renal diseases, especially in elderly male. Prolonged administration or excessive dosage may cause inhibition of testicular function. As a result, oligospermia may develop, and there may be a decrease in ejaculatory volume. Anaphylactic reactions, although rare, may occur, and treatment should be readily available. Hypersensitivity reactions, including rash and dermatitis, have been reported.

Because androgens may alter serum cholesterol concentration, caution should be used when administering these drugs to patients with a history of myocardial infarction or coronary artery disease.

Patients on oral anticoagulant therapy require close monitoring especially when androgens are started or stopped.

Diabetics: androgens may alter the metabolism of oral hypoglycemic agents or may change insulin sensitivity in patients with diabetes mellitus which may require adjustment of dosage of insulin and other hypoglycemic drugs.

## DRUG INTERACTIONS:

In diabetic patients, the metabolic effects of BoldMax may decrease blood glucose and insulin requirements.

### ADVERSE REACTIONS:

Male: Gynecomastia, excessive frequency and duration of penile erections, oligospermia. Skin and Appendages: Hirsutism, male pattern baldness and acne, gynecomastia. Fluid/electrolyte Disturbances: Retention of sodium, chloride, water, potassium, calcium, and inorganic phosphates.

Gastrointestinal: Nausea, cholestatic jaundice, alterations in liver function tests; rarely, hepatocellular neoplasms, peliosis hepatitis, hepatic adenomas, and cholestatic hepatitis. Hematologic: Suppression of clotting factors II, V, VII, & X; bleeding in patients on anti-coagulant therapy.

Nervous System: Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia.

Other: Serum lipid changes, hypercalcaemia, hypertension, oedema, priapism, and potentiation of sleep apnea

BoldMax<sup>®</sup>, androgenic (over aggressiveness) effects may be noted in a few animals. If these effects occur, they may persist for up to 6 to 8 weeks. No additional injections of Boldenone Undecylenate should be administered.

#### OVERDOSAGE:

There have been no reports of acute overdosage with the androgens.

## PATIENT MONITORING:

Serum Cholesterol, HDL, LDL, TG. Hemoglobin and Hematocrit, Hepatic function tests - AST/ALT, 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.

## DOSAGE AND ADMINISTRATION:

BoldMax<sup>®</sup> is administered by intramuscular injection. It must not be given intravenously. Intramuscular injections should be given deep in the gluteal muscle.

Males: 200-300 mg per week, given 1 time weekly.

Females: 50-75 mg per week, given 1 time weekly.

HOW SUPPLIED - Boldenone Undecylenate are supplied in 2 trade names:

- 1. Boldenone<sup>®</sup> injection, solution- Intramuscular-250 mg/ml is supplied in multiple dose 10 ml vial with Hexachrome cyan color flip cap.
- 2, BoldMax  $^{\text{@}}$  injection, solution- Intramuscular -400 mg/ml is supplied in multiple dose 10 ml vial with warm red color flip cap.

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

Keep out of reach of children.

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

Do not freeze

This drug should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Warming and shaking the vial should redissolve any crystals that may have formed during storage at temperatures lower than recommended.

Protect from sun light

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.

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