SCHEDULING STATUS: S5

PROPRIETARY NAME (AND DOSAGE FORM):

DEPO-TESTOSTERONE™ 100 mg (Injection)

COMPOSITION:

Each ml contains 100 mg testosterone cypionate with benzyl alcohol 0,9% m/v as preservative.

PHARMACOLOGICAL CLASSIFICATION:

Category A 21.7 (Male sex hormones)

PHARMACOLOGICAL ACTION:

In the eunuch and eunuchoid male, androgens act to stimulate and maintain the secondary sexual characteristics associated with the adult male. Androgens influence closure of the epiphyseal lines in males and some females, administration of androgens reduces urinary excretion of nitrogen, sodium, potassium, chloride, phosphorus and water.

INDICATIONS:

Based on a review by the National Academy of Sciences - National Research Council and/or other information, FDA has classified the indications for certain androgens as follows:

Effective - In the male:

1. Eunuchism, eunuchoidism, deficiency after castration.

2. Male climacteric symptoms when these are secondary to androgen deficiency.

3. Oligospermia.

Probably Effective - In the female or male:

1. Postmenopausal or senile osteoporosis. Androgens are without value as a primary therapy, but may be of value as adjunctive therapy. Equal or greater consideration should be given to diet, calcium balance, physiotherapy, and good general health-promoting measures.

Final classification of the less-than-effective indications requires further investigation.

CONTRA-INDICATIONS:

Carcinoma of the male breast.

Carcinoma known or suspected of the prostate.

Cardiac, hepatic or renal decompensation.

Hypercalcaemia.

Liver function impairment.

Prepubertal males.

Pregnancy.

DOSAGE AND DIRECTIONS FOR USE:

DEPO-TESTOSTERONE is for *intramuscular* use only. Dosage will vary depending upon the individual, the condition being treated, its severity, and prior androgen therapy. Because of the protracted action of **DEPO-TESTOSTERONE** injections more frequently than every two weeks are seldom required.

Eunuchism; Eunuchoidism - For complete replacement in eunuchs and eunuchoid patients, the usual dose of **DEPO-TESTOSTERONE** is 200 to 400 mg injected at intervals of three to four weeks. It is usually preferable to begin treatment with full therapeutic doses, which are later adjusted to individual requirements. Priapism is a sign of excessive dosage and is an indication for temporary withdrawal of androgen therapy.

Impotence due to Testicular Deficiency; Male Climacteric - **DEPO-TESTOSTERONE** may be given every three to four weeks in doses ranging from 200 to 400 mg.

Oligospermia - To stimulate spermatogenesis when trial androgen therapy is indicated in sub-fertile males with oligospermia, recommended dosage of **DEPO-TESTOSTERONE** is: (1) 100 to 200 mg every three to six weeks for development and maintenance of testicular function; (2) 200 mg each week for six to ten weeks for suppression which may then be followed by rebound spermatogenesis following discontinuance of the injection.

Anabolic Effect; Osteoporosis - The dosage of **DEPO-TESTOSTERONE** for anabolic effect should be adjusted according to age, sex, and the condition of the individual patient. In the majority of cases, the dose will range from 200 to 400 mg injected every three to four weeks. In addition, an adequate diet should be provided, and prolonged immobilization avoided whenever possible.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Hypercalcaemia may occur in immobilized patients, and in patients with breast cancer. In patients with cancer this may indicate progression of bony metastasis. If this occurs

the drug should be discontinued. Testosterone propionate must not be used interchangeably with testosterone cypionate, enanthate or phenylacetate due to the difference in duration of action.

Do not give intravenously.

Watch female patients closely for signs of virilization. Some effects such as voice changes may not be reversible when the drug is stopped.

Due to the prolonged action of this drug, it should be administered with caution to patients with organic heart disease of debilitation.

Patients with cardiac, renal or hepatic derangement may retain sodium and water thus forming oedema.

Priapism or excessive sexual stimulation may develop. Oligospermia and reduced ejaculatory volume may occur after prolonged administration or excessive dosage.

Hypersensitivity and gynecomastia may occur.

When any of these effects appear, the androgen should be stopped and if restarted, a lower dosage should be utilized.

The PBI may increase during androgen therapy without clinical significance.

Acne

Decreased ejaculatory volume

Gynecomastia

Oedema

Hypersensitivity, including skin manifestations and anaphylactoid reactions

Priapism

Hypercalcaemia (especially in immobile patients and those with metastatic breast carcinoma)

Local irritation

Virilization in females

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Treatment should be symptomatic and supportive.

IDENTIFICATION:

A pale yellow oily solution.

PRESENTATION:

DEPO-TESTOSTERONE 100 mg is available in a 10 ml glass vial sealed with a gray rubber stopper and secured with an aluminium overseal with a flip-off cap. Each vial is packed in an outer cardboard carton.

STORAGE INSTRUCTIONS:

Store at or below 30 °C.

Protect from light.

Keep out of reach of children

REFERENCE NUMBER:

G 2989 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

30 August 1976

Manufacturer: Pharmacia and Upjohn Company LLC, Kalamazoo, USA

NAMIBIA: NS3

Reg. No.: 14/21.7/0433

BOTSWANA: S2

Reg. No.: B9312015