

© **DEPO-TESTOSTERONE**
Testosterone cypionate injection USP

Information for the Patient

Please read this **PATIENT INFORMATION** carefully before you start using **DEPO-TESTOSTERONE** and each time you have your prescription refilled. This leaflet is a summary and does not take the place of talking to your healthcare provider about your medical condition or your treatment. If you have any questions or concerns, you should speak with your doctor or pharmacist.

ABOUT THIS MEDICATION

What the medication is used for:

Your doctor has prescribed Depo-Testosterone because your body is not making enough testosterone. The medical term for this condition is hypogonadism.

What it does:

Depo-Testosterone delivers testosterone into the bloodstream through an injection into your gluteal muscle. Depo-Testosterone helps raise your testosterone to normal levels.

When it should not be used:

- if you have prostate or breast cancer (confirmed or suspected by your doctor);
- if you have difficulty in urinating due to an enlarged prostate;
- if you have a known allergy or sensitivities to any of the ingredients contained in Depo-Testosterone, including testosterone USP that is chemically synthesized from soy (see "What the medicinal and nonmedicinal ingredients are" in this section).

Depo-Testosterone should **NOT** be used **by women**. Pregnant and breast feeding women are especially at risk. Testosterone may cause harm to your unborn baby.

What the Medicinal ingredient is:

Testosterone cypionate

What the Medicinal and Non-medical ingredient are:

Benzyl alcohol, benzyl benzoate, and cottonseed oil

What dosage forms it comes in:

Depo-Testosterone is available in one strength, 100 mg testosterone cypionate /mL.

Depo-Testosterone is available in the following packaging:
 100 mg per mL – In vials of 10 mL.

WARNINGS AND PRECAUTIONS

There is very little information from clinical trials with testosterone in the older male (>65 years of age) to support safe use for a long period of time.

Depo-Testosterone is not recommended for use in children < 18 years of age.

You should not use testosterone in an attempt to reduce weight and increase muscle, or improve athletic performance as it may cause serious health problems.

You should not use testosterone to treat sexual dysfunction or male infertility.

Depo-Testosterone contains benzyl alcohol. Benzyl alcohol has been reported to be associated with a fatal "Gasping Syndrome" in premature infants.

Before using Depo-Testosterone, talk to your doctor if you:

- have difficulty urinating due to an enlarged prostate. Older patients may have a higher risk of developing an enlarged prostate or prostate cancer;
- have prostate cancer (confirmed or suspected);
- have liver, kidney or heart disease;
- have high blood pressure (hypertension);
- have diabetes;
- have breathing problems during sleep (sleep apnea).

Drug Abuse and Dependence: Depo-Testosterone contains testosterone, which is a controlled substance under Schedule G of the Food and Drugs Act.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other drugs or herbal products, even those without a prescription.

Drugs that may interact with Depo-Testosterone include:

- Insulin
- Corticosteroids
- Propranolol
- Warfarin

PROPER USE OF THIS MEDICATION

Depo-Testosterone should be used only under the supervision of a doctor, with regular follow-up.

Usual dose:

To treat hypogonadism, 200 mg is given intramuscularly (in the muscle) every two weeks.

Overdose:

Contact your doctor or pharmacist immediately if you suspect an overdose.

Missed Dose:

If you have missed a dose of Depo-Testosterone, you should contact your doctor to schedule your next injection.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Depo-Testosterone can have side effects. The following side effects have been reported for testosterone products:

- skin irritation or redness or rash at the application site;
- increased prostatic specific antigen (PSA);
- enlarged prostate (benign prostatic hyperplasia);
- an increase in red blood cell count, (hematocrit and hemoglobin);
- acne;
- change in mood, depression;
- prolonged or painful erection;
- sleep disturbances caused by breathing problems;
- aggression or aggressive behaviour;
- breast enlargement and breast pain;
- loss of hair and baldness;
- high blood pressure;
- weight gain;
- headache, dizziness.

This is not a complete list of side effects. For any unexpected effects while taking Depo-Testosterone, contact your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/ Effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Urinary symptoms (i.e. change in frequency /color, dribbling, pain on urination, straining, weak stream, small amounts)		√	
Common (after prolonged use)	Breast enlargement or breast pain		√	
Uncommon	Swelling of ankles and legs (in patients with heart, kidney or liver damage)			√
Uncommon	Erections that are too frequent or continue for too long, or are painful.		√	
Uncommon	Liver problems, with symptoms such as nausea, vomiting, along with yellowed or darkened skin			√

HOW TO STORE IT

Store Depo-Testosterone at controlled room temperature (15°C-30°C). Protect from light.

Keep in a safe place out of reach of children and pets.

You should not use your medication after the expiration date printed on the carton and label.

Keep all medications out of the reach of children. This medication could harm them.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: cadrm@hc-sc.gc.ca

By regular mail:
Canadian Adverse Drug Reaction Monitoring Program
(CADRMP)
Marketed Health Products Directorate
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full prescribing information, prepared for health professionals can be found at:

<http://www.pfizer.ca>

or by contacting the sponsor, Pfizer Canada Inc., at:
1-800-463-6001.

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Last revised: 03 July 2007