

PART III: CONSUMER INFORMATION

DEPO-TESTOSTERONE Testosterone cypionate injection USP

This leaflet is part III of a three-part "Product Monograph" and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DEPO-TESTOSTERONE. Contact your doctor or pharmacist if you have any questions about the drug.

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 nonmedicinal ingredients 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.

DEPO-TESTOSTERONE can cause changes in your vision. It is called chorioretinopathy.

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. The preservative benzyl alcohol has been associated with serious adverse events, including the "gasping syndrome" (difficulty in catching breath, low blood pressure, slow heart rate), and death in pediatric patients. Premature and low-birth weight infants may be more likely to develop toxicity.

Pregnancy: Benzyl alcohol can cross the placenta.

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);
- have heart or blood vessels problems or a history of these problems such as heart attack, stroke, or blood clots in the lungs or the legs.

Drug Abuse and Dependence: DEPO-TESTOSTERONE contains testosterone. Testosterone is a controlled substance because some people take it in high doses (abuse it), even if their body is making enough testosterone. Taking too much (abusing) testosterone can cause serious health problems, which can even lead to death (see **Overdose**).

Individuals who have abused testosterone may experience withdrawal symptoms lasting for weeks or months which include, but are not limited to: changes in mood, and appetite, as well as fatigue, insomnia, decreased sex drive and loss of function of the testes and ovaries.

Drug dependence in individuals using approved doses of testosterone for approved indications has not been documented.

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 include:

- Insulin
- Corticosteroids
- Propranolol
- Warfarin

PROPER USE OF THIS MEDICATION

DEPO-TESTOSTERONE should only be administered by a health care professional.

When you are given DEPO-TESTOSTERONE, your blood testosterone should be checked on a regular basis.

Usual dose:

200 mg is given intramuscularly (in the muscle) every two weeks.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms

Taking too much (abusing) testosterone for a long time can cause serious health problems, which can even lead to death. Some of the health problems include effects on the cardiovascular system, reproductive system and the liver, as well as serious psychiatric problems.

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;
- increased or irregular heart rate, blood clot in the lungs or the legs;

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			√
Uncommon	Heart Attack: Crushing chest pain or heaviness, sharp pain in the chest, coughing blood, or sudden shortness of breath			√
Uncommon	Stroke: Sudden severe headache or worsening of headache, vomiting, dizziness, fainting, disturbance of vision or speech, or weakness or numbness in the face, arm or leg			√
Unknown	Chorioretinopathy: blurred vision, blind spot, objects seeming smaller or distortion of straight lines		√	

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

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9****

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

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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