

**PART III: CONSUMER INFORMATION**

**TESTOSTERONE CYPIONATE INJECTION USP**

Testosterone cypionate injection USP  
100 mg/mL sterile solution

This leaflet is part III of a three-part “Product Monograph” published when Testosterone Cypionate Injection USP was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Testosterone Cypionate Injection USP. 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 Testosterone Cypionate Injection USP because your body is not making enough testosterone. The medical term for this condition is hypogonadism.

**What it does:**

Testosterone Cypionate Injection USP delivers testosterone into the bloodstream through an injection into your gluteal muscle. Testosterone Cypionate Injection USP 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 Testosterone Cypionate Injection USP, including testosterone USP that is chemically synthesized from soy (see “What the medicinal and nonmedicinal ingredients are” in this section).

Testosterone Cypionate Injection USP 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:**

Testosterone Cypionate Injection USP is available in one strength, 100 mg testosterone cypionate /mL.

Testosterone Cypionate Injection USP is available in 10 mL multidose vials.

**LATEX FREE STOPPER** - Stopper contains no dry natural rubber.

**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.

Testosterone Cypionate Injection USP is not recommended for use in children < 18 years of age.

Testosterone Cypionate Injection USP 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.

Testosterone Cypionate Injection USP 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 Testosterone Cypionate Injection USP, 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:** Testosterone Cypionate Injection USP 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

Testosterone Cypionate Injection USP should only be administered by a health care professional.

When you are given Testosterone Cypionate Injection USP, 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 Testosterone Cypionate Injection USP, you should contact your doctor to schedule your next injection.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Testosterone Cypionate Injection USP 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 Testosterone Cypionate Injection USP, 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)			✓
	Erections that are too frequent or continue for too long, or are painful.		✓	
	Liver problems with symptoms such as nausea, vomiting, along with yellowed or darkened skin			✓
	<b>Heart Attack:</b> Crushing chest pain or heaviness, sharp pain in the chest, coughing blood, or sudden shortness of breath			✓
Unknown	<b>Stroke:</b> 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			✓
	<b>Chorioretinopathy:</b> blurred vision, blind spot, objects seeming smaller or distortion of straight lines		✓	

## HOW TO STORE IT

Store Testosterone Cypionate Injection USP at controlled room temperature (15°C - 30°C). Protect from light and freezing.

Keep in a safe place out of reach of children and pets. Discard within 28 days of initial use.

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 Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

## MORE INFORMATION

This document, plus the full Product Monograph prepared for health professionals, can be obtained by contacting the sponsor, Sandoz Canada Inc., at: 1-800-361-3062

or

by written request at:

110 Rue De Lauzon

Boucherville, (QC), Canada

J4B 1E6

or by e-mail at :

[medinfo@sandoz.com](mailto:medinfo@sandoz.com)

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