

TESTO-100- testosterone,usp pellet, implantable
Advanced Pharmaceutical Technology, Inc.

Testo-100

Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious or you notice any side effects listed in this leaflet, please tell your doctor or your pharmacist.

What testosterone Implants are and what they are used for

Testosterone implants are pellets containing 100mg of the active ingredient testosterone. These implants are used in hormone replacement therapy in men. Testosterone is a natural male hormone, known as an androgen, which controls normal sexual development in men.

Testosterone implants are used in testosterone replacement therapy in men with low or no natural testosterone (a condition known as hypogonadism).

Before you are given Testosterone Implants

Do not use Testosterone Implants if you:

- are allergic (hypersensitive) to testosterone
- have prostate cancer or breast cancer

Take special care with Testosterone Implants:

Extra supervision by your doctor may be necessary in some cases: particularly the elderly.

-> Tell your doctor if you have ever had:

- heart disease
- kidney disease
- liver disease
- high blood pressure
- epilepsy
- migraine
- cancer of the bone

- sleep apnea (temporary stopping of breathing during your sleep), If this gets worse during treatment you should also tell your doctor.

Blood tests may be affected.

Children and adolescents

Safety and efficacy have not been adequately determined in children and adolescents.

Extra supervision by the doctor is necessary in the treatment of young boys since male hormones may cause early sexual development and delay growth.

Testosterone implants should not be used to enhance ability in sports as it carries serious health risks.

Taking other medicines

Other medicines may affect how Testosterone Implants work or Testosterone Implants may affect how they work.

These include:

- Certain medicines that change the amount of enzymes to be made in the liver e.g. medicines used to treat epilepsy (phenobarbital). These drugs may affect the levels of testosterone in your body and your doctor may need to adjust the dose of your Testosterone Implants.
- Certain medicines that thin the blood (anti-coagulants).

Your doctor may need to adjust the dose of your anticoagulant.

- Medicines for diabetes. Your doctor may need to adjust the dose of your medicine for diabetes.
- Other hormone medicines (for example corticosteroids or ACTH, used to treat various conditions such as rheumatism, arthritis, allergic conditions and asthma).

-> Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

Laboratory Tests

Testosterone Implants may also affect the results of some laboratory tests (e.g. thyroid gland and liver function tests). Tell your doctor or the laboratory staff that you are using Testosterone Implants.

Pregnancy and breast-feeding

Testosterone Implants are not for use in women.

Testosterone Implants must not be taken during pregnancy or when you are breast feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

As far as known Testosterone Implants have no adverse effects on alertness or concentration.

How you are given Testosterone Implants

Testosterone Implants are normally given by a doctor.

Testosterone Implants are inserted under the skin into the lower abdominal wall or buttock by your doctor.

You are usually given a local anaesthetic in this area before the implant is inserted and the small cut made is dressed with a bandage afterwards. The implant usually lasts for 4 or 5 months. The dose depends on your illness and how bad it is.

Your doctor will decide the dose.

In men a dose of 100-400mg is usual, but this depends on each individual.

If you are given more Testosterone than you should:

-> If you think you have been given too much Testosterone, tell your doctor straight away, as they may wish to remove the implant. The following effects may happen:

- frequent erections in men
- changes in your red blood cells (polycythemia), which your doctor may monitor for.

Possible side effects

Like all medicines, Testosterone Implants can have side effects, although not everybody gets them.

The most common side effect with the Implant are:

- infection, bruising or bleeding at the implantation site
- the implant may start to come out of the implantation site.

The other possible side effects include:

- worsening of the early stages of prostate cancer
- Increased levels of a blood marker which is associated with prostate cancer (PSA increased)
- growth of the prostate gland
- prolonged painful erection
- ejaculation disorder
- increase or decrease in sexual desire
- changes in sperm formation
- enlargement of breasts
- acne
- itching (pruritus)
- high blood pressure (hypertension)
- swollen legs or ankles (caused by water retention)
- changes in your red blood cells (polycythemia)
- changes in cholesterol levels

- muscle pain (myalgia)
- feeling sick
- changes in mood, feelings of depression or nervousness.
- increased risk of water retention, especially if your heart and liver are not working properly

In young boys, it may cause:

- early sexual development
- erections occurring more often than normal
- enlarged penis
- delayed growth

-> If you are having laboratory tests, tell your doctor or laboratory staff that you are using Testosterone Implants.

-> If any other side effects get serious, or if you notice any side effects not listed, please tell your doctor or pharmacist.

How to store Testosterone Implants

Keep out of reach of children.

Do not store above 25 °C.

Store in original package.

Do not use Testosterone Implants after the expiry date stated on the package and ampule.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help in protecting the environment.

Further Information

What Testosterone Implants contain

100mg Implant

- The active substance is testosterone 100mg per implant.

other inert ingredients - polyvinylpyrrolidone USP 2mg and stearic acid 1mg

What Testosterone Implants look like and contents of the pack

Testosterone Implants are white to pale yellow pellets.

Each sterile implant is supplied simply in a sealed glass ampule.

Manufactured by:

ADVANCED PHARMACEUTICAL TECHNOLOGY

132 South Central Avenue
Elmsford, NY 10523

Patient Leaflet

TESTO-100

TESTOSTERONE 100MG

PELLET IMPLANT

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What Testosterone Implants look like and contents of the pack

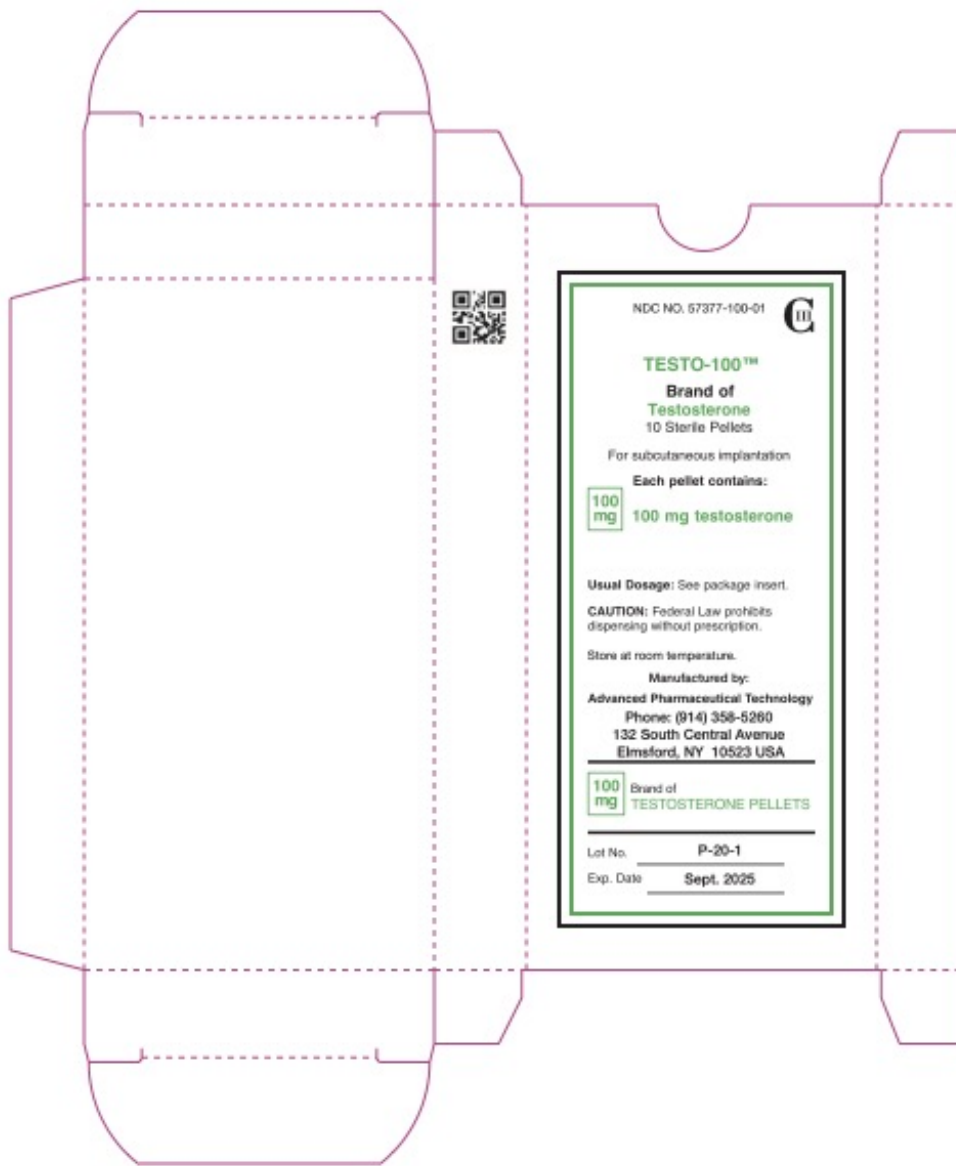
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Manufactured by:

**ADVANCED PHARMACEUTICAL TECHNOLOGY
132 South Central Avenue, Elmsford, NY 10523**

Testo-100 (57377-100-01)



Testo-100

Brand of

Testosterone

10 Sterile Pellets

For subcutaneous implantation

Each pellet contains:

100mg testosterone

Usual Dosage:See package insert.

Caution:

Federal Law prohibits dispensing without prescription.

Store at room temperature.

TESTO-100

testosterone,usp pellet, implantable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:57377-100
Route of Administration	SUBCUTANEOUS	DEA Schedule	CIII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TESTOSTERONE (UNII: 3XMK78S47O) (TESTOSTERONE - UNII:3XMK78S47O)	TESTOSTERONE	100 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57377-100-01	10 in 1 AMPULE; Type 0: Not a Combination Product	01/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		01/01/2024	

Labeler - Advanced Pharmaceutical Technology, Inc. (023237884)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Pharmaceutical Technology, Inc.		023237884	manufacture(57377-100) , pack(57377-100)

Revised: 9/2024

Advanced Pharmaceutical Technology, Inc.