

Testosterone Cas No. : 58-22-0

This medicated gel contains testosterone. It is used for hormone replacement in men who are not able to produce enough testosterone (e.g., hypogonadism). This medication is absorbed through the skin, enters your bloodstream, and helps your body reach normal testosterone levels. Testosterone helps the body to produce sperm and to develop and maintain the male sexual characteristics (masculinity), such as a deep voice and body hair.

Active Pharmaceuticals Ingredients Manufacturers



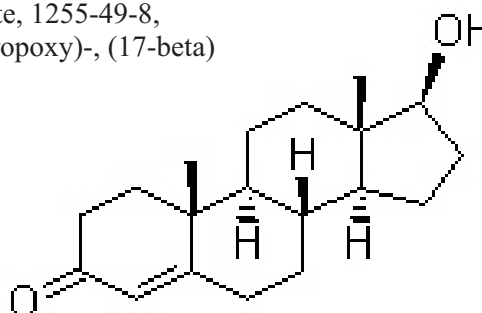
Taj Pharma PDF

Taj Pharmaceuticals Ltd.**Testosterone****CAS No. : 58-22-0****Synonyms:**

Retandrol, Testolent, Testosterone phenylpropionate, Testosterone phenpropionate, Testosterone, hydrocinnamate, Testosterone 17-phenylpropionate, Testosterone hydrocinnamate, T9890_SIGMA, EINECS 215-014-4, NSC 26643, BB_NC-0581, NSC26643, TESTOSTERONE PHENYL PROPIONATE, ZINC03881605, 17beta-Hydroxyandrost-4-en-3-one 3-phenylpropionate, LS-148821, C14667, 4-Androsten-17beta-ol-3-one 17-phenylpropionate, 1255-49-8, Androst-4-en-3-one, 17-(1-oxo-3-phenylpropoxy)-, (17-beta)-Phenylpropoxy)-, (17-beta)

Chemical data

Chemical Name: Testosterone
Chemical Formula: C₁₉H₂₈O₂
CAS Number: 58-22-0

**USES**

This medicated gel contains testosterone. It is used for hormone replacement in men who are not able to produce enough testosterone (e.g., hypogonadism). This medication is absorbed through the skin, enters your bloodstream, and helps your body reach normal testosterone levels.

Testosterone helps the body to produce sperm and to develop and maintain the male sexual characteristics (masculinity), such as a deep voice and body hair. It also helps to maintain muscle and prevent bone loss, and is necessary for natural sexual ability/desire.
This drug should not be used by women.

HOW TO USE

Apply the medication as directed to the clean, dry skin of the shoulders/upper arms, once daily in the morning or as directed by your doctor. Certain brands of this medication may also be applied to the lower stomach (abdomen). Check your Patient Information Leaflet or ask your pharmacist if your brand may be applied to the lower abdomen. Dosage is based on your medical condition and response to therapy.
Avoid applying gel to skin with open sores or to broken, irritated skin. Do not apply this medication to the genitals (penis or scrotum).

After applying this medication, wash your hands thoroughly with soap and water to reduce the possibility of spreading the medicine from your hands to other people.

Use this medication regularly in order to get the most benefit from it. To help you remember, use it at the same time each day. Allow this medication to dry completely on the skin before getting dressed. After applying the gel, wait several hours before showering or swimming (2 to 6 hours depending on brand) to make sure all the drug is absorbed. If you are unsure how long you must wait, check the manufacturer's Patient Information Leaflet or ask your pharmacist.

SIDE EFFECTS

Nausea, vomiting, headache, dizziness, hair loss, trouble sleeping, change in sexual desire, redness/swelling of the skin, change in skin color, or acne may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.



Taj Pharmaceuticals Ltd.
Testosterone

CAS NO- 58-22-0



Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

In patients with diabetes, especially those taking insulin, testosterone may decrease your blood sugar. Be prepared to treat low blood sugar while you are using this medication. Symptoms of low blood sugar include shakiness, nervousness, rapid pulse, and sweating. If you are experiencing these symptoms, consult your doctor.

For males, in the very unlikely event you have a painful or prolonged erection lasting 4 or more hours, stop using this drug and seek immediate medical attention, or permanent problems could occur.

PRECAUTIONS

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: breast cancer (males), prostate cancer.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver problems, prostate problems (e.g., enlarged prostate or BPH), heart problems, kidney problems, diabetes, high cholesterol level, lung disease, obesity, difficulty breathing during sleep (apnea), high blood pressure, bone cancer.

Direct contact with the application site can spread this medication to others. Protect others from direct skin contact with the application site. This is especially important for women (especially pregnant women) and children. You can use clothing (e.g., long-sleeved shirt) to cover the area, but if you expect to have direct contact with someone else, you should wash the application site with soap and water in advance. Should anyone's skin directly contact the application site, their skin should be washed immediately with soap and water.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is less than 12 hours until your next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom or near an open flame. Keep all medicines away from children and pets, and throw out used gel packets in a secure trash can.

DOSAGE

The recommended starting dose of Testosterone is 5 g once daily (preferably in the morning) to clean, dry, intact skin of the shoulders and upper arms and/or abdomen. Testosterone must not be applied to the genitals. Testosterone is supplied as either a pump or in individual packets. After applying the gel, the application site should be allowed to dry for a few minutes prior to dressing. Avoid fire, flames or smoking until the gel has dried since alcohol based products, including

Testosterone, are flammable. Hands should be washed with soap and water after Testosterone has been applied. Patients should be instructed to prime the pump before using it for the first time by fully depressing the pump mechanism (actuation) 3 times and discard this portion of the product to assure precise dose delivery. After the priming procedure, patients should completely depress the pump one time (actuation) for every 1.25 g (Testosterone Pump) of product required to achieve the daily prescribed dosage.



The product may be delivered directly into the palm of the hand and then applied to the desired application sites, either one pump actuation at a time or upon completion of all pump actuations required for the daily dose. Alternatively, the product can be applied directly to the application sites. Application directly to the sites may prevent loss of product that may occur during transfer from the palm of the hand onto the application sites. Table 1 has specific dosing guidelines for adult males when the 75 g Testosterone Pump is used.

DRUG DESCRIPTION

Testosterone: A "male hormone" -- a sex hormone produced by the testes that encourages the development of male sexual characteristics, stimulates the activity of the male secondary sex characteristics, and prevents changes in them following castration. Chemically, testosterone is 17-beta-hydroxy-4-androstene-3-one.

Testosterone is the most potent of the naturally occurring androgens. The androgens cause the development of male sex characteristics, such as a deep voice and a beard; they also strengthen muscle tone and bone mass.

High levels of testosterone appear to promote good health in men, for example, lowering the risks of high blood pressure and heart attack. High testosterone levels also correlate with risky behavior, however, including increased aggressiveness and smoking, which may cancel out these health benefits.

Testosterone may be given to treat medical conditions, including female (but not male) breast cancer, hypogonadism (low gonadal function) in the male, cryptorchism (nondescent of the testis into the scrotum), and menorrhagia (irregular periods).

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

Information: The information on this web page is provided to help you to work safely, but it is intended to be an overview of hazards, not a replacement for a full Material Safety Data Sheet (MSDS). MSDS forms can be downloaded from the web sites of many chemical suppliers. Also that the information on the PTCL Safety web site, where this page was hosted, has been copied onto many other sites, often without permission. If you have any doubts about the veracity of the information that you are viewing, or have any queries, please check the URL that your web browser displays for this page. If the URL begins "www.tajapi.com/www/Denatonium Benzoate.htm/" the page is maintained by the Safety Officer in Physical Chemistry at Oxford University. If not, this page is a copy made by some other person and we have no responsibility for it.

The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

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

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.

This leaflet was prepared by
Taj Pharmaceuticals Limited,
Mumbai (India).

MPSTJ278

Last revised: 29 August 2009