

Testosterone Injection

Important warning:

Testosterone undecanoate injection (Aveed[®]) may cause serious breathing problems and allergic reactions, during or immediately after the injection. The injection should be given by a doctor or nurse in a healthcare setting where these problems or reactions can be treated. You will need to remain in the healthcare setting for at least 30 minutes after you receive your injection. Tell your doctor or nurse immediately if you experience any of the following symptoms during or after your injection: tightening of your throat, difficulty breathing, difficulty swallowing, shortness of breath, cough or urge to cough, chest pain, dizziness, fainting, sweating, rash, hives, or itching.

Because of the risks of serious breathing problems and allergic reactions, testosterone undecanoate injection (Aveed[®]) is only available through a special program. This program is called the Aveed[®] REMS. Your doctor must be enrolled in this program before you can receive this medication. Ask your doctor for more information about this program and how you will receive your medication.

You will be given the Medication Guide when you begin treatment with testosterone injection. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit <https://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> (<https://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>) to obtain the Medication Guide.

Why is this medicine prescribed?

Testosterone injection is used to treat low or no testosterone levels, stimulate puberty in males with delayed puberty, and certain types of breast cancer. Testosterone is in a class of medications called androgenic hormones. Testosterone is a male sex hormone responsible for development and functioning of male sexual organs and typical male characteristics. Testosterone injection works by replacing the testosterone that is normally produced naturally in the body. When used to treat breast cancer, testosterone works by stopping the release of estrogen.

Are there other uses for this medicine?

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

How should this medicine be used?

Testosterone injection comes as a solution (liquid) to be injected into a muscle by a doctor or nurse in an office setting or clinic. It also comes as a solution (liquid) to be injected subcutaneously (under the skin) once a week by yourself or a caregiver. Testosterone also comes as pellets to be implanted under the skin by a doctor or nurse in an office setting or clinic.

Use subcutaneous testosterone injection exactly as directed. Do not use more or less of it or use it more often than prescribed by your doctor.

Your first dose of subcutaneous testosterone injection will be given in your doctor's office. After that, you may be allowed to inject the medicine yourself or a caregiver may give it to you. Your healthcare provider will show you or your caregiver how to inject testosterone. Read the written instructions that come with it before injecting your first dose. Be sure that you understand these instructions, and ask your healthcare provider if you have any questions.

Always look at testosterone solution before you inject it. It should be clear to light yellow in color and free of visible particles. Do not use it if it is cloudy, contains visible particles, or if the expiration date on the package has passed.

You can inject testosterone in the left or right side of your stomach except your navel (belly button) and the area 2 inches around it. Do not inject into an area where the skin is tender, bruised, red, or hard or where you have scars, tattoos, or stretch marks.

Testosterone injection may control your symptoms but will not cure your condition. Your doctor may adjust your dose of testosterone depending on the amount of testosterone in your blood during your treatment and your reaction to the medication.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

What special precautions should I follow?

Before receiving testosterone injection,

- tell your doctor and pharmacist if you are allergic to this drug, any part of this drug, or any other drugs, foods or substances. Tell your doctor or pharmacist about the allergy and what symptoms you had.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take while receiving testosterone injection. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- if you are male, tell your doctor if you have breast cancer or have or may have prostate cancer. Your doctor may tell you that you should not receive testosterone injection.
- tell your doctor if you have or have ever had sleep apnea (breathing stops for short periods of time during sleep); urinary problems; benign prostate hyperplasia (BPH; an enlarged prostate); high blood levels of calcium; cancer; diabetes; depression or other mental illness; high blood pressure, heart disease, a heart attack, or a stroke; blood clots; higher than normal red blood cell counts; or liver, kidney, or lung disease.
- women who can become pregnant should not use this medication. Testosterone may cause deepening of voice, hair growth in unusual places, genital enlargement, decrease in breast size, male-pattern hair loss, and unusual menstrual cycles in women. If testosterone is used by women who are pregnant, may become pregnant, or are breastfeeding, it may harm the baby.
- you should know that testosterone may cause serious side effects if used at higher doses or in ways other than directed by a doctor. These side effects may include a heart attack, heart failure, or other heart problems; stroke and mini-stroke; liver disease; seizures; or mental health changes such as depression, mania (frenzied, abnormally excited mood), aggressive or unfriendly behavior, hallucinations (seeing things or hearing voices that do not exist), or delusions (having strange thoughts or beliefs that have no basis in reality). People who use higher doses of testosterone than recommended by a doctor may also experience withdrawal symptoms such as

depression, extreme tiredness, craving, irritability, restlessness, loss of appetite, inability to fall asleep or stay asleep, or a decreased sex drive, if they suddenly stop using testosterone. Be sure to use testosterone injection exactly as directed by your doctor.

- you should know that testosterone may cause an increase in blood pressure. This may increase your risk of having a heart attack or stroke that may be life-threatening. If you experience any of the following symptoms, call your doctor immediately: chest pain; shortness of breath; pain in the arms, back, neck, or jaw; slow or difficult speech; dizziness or faintness; or weakness or numbness of an arm or leg. Your doctor may check your blood pressure before starting treatment and regularly while you are receiving testosterone injection.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What side effects can this medicine cause?

Testosterone injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- acne
- pain, redness, bruising, bleeding, or hardness at injection site
- tiredness
- difficulty falling asleep or staying asleep
- mood swings
- weight gain
- headache
- joint pain
- back pain

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING or SPECIAL PRECAUTIONS sections, call your doctor immediately:

- lower leg pain, swelling, warmth, or redness
- swelling of the hands, feet, ankles, or lower legs
- difficulty breathing, especially during sleep
- erections that happen too often or that last too long
- difficulty urinating, weak urine flow, frequent urination, sudden need to urinate right away, blood in the urine
- nausea or vomiting, yellowing of the skin or eyes, dark urine, or pain in the upper right part of the stomach
- mood changes including depression, anxiety, or becoming suicidal (thinking about harming or killing oneself or planning or trying to do so)
- enlarged or painful breasts

Testosterone injection may cause a decrease in the number of sperm (male reproductive cells) produced, especially if it is used at high doses. Talk to your doctor about the risks of using this medication if you are a man and would like to have children.

Testosterone may increase the risk of developing prostate cancer. Talk to your doctor about the risks of receiving this medication.

Testosterone injection may cause the bones to mature more quickly than normal in children who receive the medication. This means that the children may stop growing sooner than expected and may have a shorter than expected adult height. Testosterone may also cause precocious puberty (early puberty) in children and teenagers.

Testosterone injection may cause other side effects. Call your doctor if you have any unusual problems while receiving this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<https://www.fda.gov/Safety/MedWatch> (<https://www.fda.gov/Safety/MedWatch>)) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep testosterone enanthate injection (Xyosted[®]) in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from light, excess heat and moisture (not in the bathroom). Do not refrigerate or freeze.

Keep all medication out of sight and reach of children as many containers are not child-resistant. Always lock safety caps. Place the medication in a safe location – one that is up and away and out of their sight and reach <https://www.upandaway.org> (<https://www.upandaway.org/>)

Dispose of unneeded medications in a way so that pets, children, and other people cannot take them. Do not flush this medication down the toilet. Use a medicine take-back program. Talk to your pharmacist about take-back programs in your community. Visit the FDA's Safe Disposal of Medicines website <https://goo.gl/c4Rm4p> (<https://goo.gl/c4Rm4p>) for more information.

What should I do in case of overdose?

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> (<https://www.poisonhelp.org/help>). If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your testosterone levels to see if they are low before you begin to receive testosterone injection. Your doctor may order certain tests to check your body's response to testosterone injection.

Before having any laboratory test, tell your doctor and the laboratory personnel that you are receiving testosterone injection.

Do not let anyone else use your testosterone enanthate injection. Testosterone is a controlled substance. Prescriptions may be refilled only a limited number of times; ask your pharmacist if you have any questions.

Keep a written list of all of the prescription and nonprescription (over-the-counter) medicines,

vitamins, minerals, and dietary supplements you are taking. Bring this list with you each time you visit a doctor or if you are admitted to the hospital. You should carry the list with you in case of emergencies

Brand name(s)

- Aveed[®]
- Azmiro[®]
- Delatestryl[®]¶
- Depo-Testosterone[®]
- Testopel[®]
- Xyosted[®]
- also available generically

Other name(s)

- testosterone cypionate
- testosterone enanthate
- testosterone undecanoate

¶ This branded product is no longer on the market. Generic alternatives may be available.

This report on medications is for your information only, and is not considered individual patient advice. Because of the changing nature of drug information, please consult your physician or pharmacist about specific clinical use.

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Testosterone Topical

Important warning:

Testosterone topical products may harm women and children who touch your skin where it has been applied. Take precautions to be sure that others will not contact testosterone gel or solution that is on your skin. After you apply testosterone gel or solution, allow the medication to dry for a few minutes and then put on clothing that completely covers the area so that no one will touch your bare skin. When you have finished applying the medication, wash your hands with soap and water to remove any medication that may be left on your hands.

Do not let anyone touch your skin in the area where you applied testosterone gel or solution. If you expect to have skin-to-skin contact with another person, wash the area very well with soap and water. If anyone touches skin covered with testosterone that has not been washed, that person should wash their skin with soap and water as soon as possible.

Women or children that touch skin treated with testosterone products, may develop certain symptoms. Call a doctor immediately if a woman develops the following symptoms: growth of hair in new places on the body or acne. Call the child's doctor immediately if a child develops any of the following symptoms: enlarged genitals, growth of pubic hair, increased erections, increased sexual desire, or aggressive behavior.

You will be given the Medication Guide when you begin treatment with testosterone topical and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit <https://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> (<https://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>) to obtain the Medication Guide.

Why is this medicine prescribed?

Testosterone topical is used to treat low or no testosterone levels in men. Testosterone is in a class of medications called androgenic hormones. Testosterone is a male sex hormone responsible for development and functioning of male sexual organs and typical male characteristics. Testosterone topical works by replacing the testosterone that is normally produced by the body.

Are there other uses for this medicine?

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

How should this medicine be used?

Topical testosterone comes as a gel and solution to apply to the skin. It is applied once a day in the morning. To help you remember to apply testosterone topical, apply it at around the same time every day.

Use testosterone topical exactly as directed. Do not apply more or less of it or apply it more often than prescribed by your doctor.

Apply testosterone topical products after you take a bath or shower. Read the manufacturer's

patient information about your topical testosterone product for information about when you can wash, shower, bath, or swim after you apply the medication.

Do *not* apply any testosterone topical products to your penis or scrotum or to skin that has sores, cuts, or irritation.

Be careful not to get testosterone topical in your eyes. If you get testosterone topical in your eyes, wash them right away with warm, clean water. Call a doctor if your eyes become irritated.

Testosterone topical comes in single use tubes, packets, and a multiple-use pump. The pump releases a specific amount of testosterone each time the top is pressed. Your doctor or pharmacist will tell you how many times to press the pump for each dose, and how many doses your pump contains.

Before you use a testosterone topical product for the first time, read the written instructions for use that come with the medicine. This will tell you how to use it. Read it carefully. Ask your doctor or pharmacist if you have any questions on how to use the medicine.

Testosterone gel and solution may catch fire. Stay away from open flames and do not smoke while you are applying it and until the gel or solution has dried completely.

Your doctor may adjust your dose of testosterone depending on the amount of testosterone in your blood during your treatment.

Testosterone topical may control your symptoms but will not cure your condition. Continue to use testosterone topical even if you feel well. Do not stop using testosterone topical without talking to your doctor. If you stop using testosterone topical, your symptoms may return.

What special precautions should I follow?

Before using testosterone topical products,

- tell your doctor and pharmacist if you are allergic to this drug, any part of this drug, or any other drugs, foods, or substances. Tell your doctor or pharmacist about the allergy and what symptoms you had.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take while using testosterone topical products. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have breast cancer or have or may have prostate cancer. Your doctor will probably tell you that you should not use testosterone topical products.
- tell your doctor if you have or have ever had sleep apnea (breathing stops for short periods of time during sleep); difficulty urinating or other urinary problems; benign prostate hyperplasia (BPH; an enlarged prostate); high blood levels of calcium; diabetes; or heart, kidney, liver, or lung disease.
- you should know that testosterone is only for use in adult men. Children, teenagers, and women should not use this medication. Testosterone may stop bone growth and cause precocious puberty (early puberty) in children and teenagers. Testosterone may cause deepening of voice, hair growth in unusual places, genital enlargement, decrease in breast size, male-pattern hair loss, and unusual menstrual cycles in women. If testosterone is used by women who are pregnant, may become pregnant, or are breastfeeding, it may harm the baby.

- you should know that testosterone may cause serious side effects if used at higher doses or in ways other than directed by a doctor. These side effects may include a heart attack, heart failure, or other heart problems; stroke and mini-stroke; liver disease; seizures; or mental health changes such as depression, mania (frenzied, abnormally excited mood), aggressive or unfriendly behavior, hallucinations (seeing things or hearing voices that do not exist), or delusions (having strange thoughts or beliefs that have no basis in reality). People who use higher doses of testosterone than recommended by a doctor may also experience withdrawal symptoms such as depression, extreme tiredness, craving, irritability, restlessness, loss of appetite, inability to fall asleep or stay asleep, or a decreased sex drive, if they suddenly stop using testosterone topical. Be sure to use testosterone topical exactly as directed by your doctor.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget to take a dose?

Apply the missed dose as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not apply a double dose to make up for a missed dose.

What side effects can this medicine cause?

Testosterone topical may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- decreased sexual desire
- acne
- headache
- teary eyes
- dry or itchy skin
- diarrhea
- skin redness or irritation
- nausea or vomiting

Some side effects can be serious. If you experience any of the following symptoms, call your doctor immediately:

- lower leg pain, swelling, warmth, or redness
- sudden shortness of breath, chest pain, dizziness or faintness
- swelling of the hands, feet, ankles, or lower legs
- slow or difficult speech
- weakness or numbness of an arm or leg
- difficulty breathing, especially during sleep
- erections that happen too often or that last too long
- difficulty urinating, weak urine flow, frequent urination, sudden need to urinate right away

- yellowing of the skin or eyes
- enlarged or painful breasts

Testosterone topical may cause a decrease in the number of sperm (male reproductive cells) produced, especially if it is used at high doses. Talk to your doctor about the risks of using this medication if you are a man and would like to have children.

Testosterone may increase the risk of developing prostate cancer. Talk to your doctor about the risks of using this medication.

Testosterone topical may cause other side effects. Call your doctor if you have any unusual problems while using this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<https://www.fda.gov/Safety/MedWatch>) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Store testosterone topical products in a safe place so that no one else can use it accidentally or on purpose. Keep track of how much medication is left so you will know if any is missing.

Keep all medication out of sight and reach of children as many containers are not child-resistant. Always lock safety caps. Place the medication in a safe location – one that is up and away and out of their sight and reach <https://www.upandaway.org> (<https://www.upandaway.org/>)

Dispose of unneeded medications in a way so that pets, children, and other people cannot take them. Do not flush this medication down the toilet. Use a medicine take-back program. Talk to your pharmacist about take-back programs in your community. Visit the FDA's Safe Disposal of Medicines website <https://goo.gl/c4Rm4p> (<https://goo.gl/c4Rm4p>) for more information.

What should I do in case of overdose?

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> (<https://www.poisonhelp.org/help>). If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests to check your testosterone levels to see if they are low before you begin to use testosterone topical. Your doctor will also order certain lab tests to check your body's response to testosterone.

Before having any laboratory test, tell your doctor and the laboratory personnel that you are using testosterone topical.

Do not let anyone else use your medication. Testosterone topical is a controlled substance.

Prescriptions may be refilled only a limited number of times; ask your pharmacist if you have any questions.

Keep a written list of all of the prescription and nonprescription (over-the-counter) medicines, vitamins, minerals, and dietary supplements you are taking. Bring this list with you each time you visit a doctor or if you are admitted to the hospital. You should carry the list with you in case of emergencies.

Brand name(s)

- Androgel[®]
- Axiron[®] ¶
- Fortesta[®] ¶
- Testim[®]
- Vogelxo[®]
- also available generically

¶ This branded product is no longer on the market. Generic alternatives may be available.

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