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Testosterone: Patient drug information

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(For additional information <u>see "Testosterone: Drug information"</u> and <u>see "Testosterone: Pediatric drug</u> <u>information"</u>)

Brand Names: US

Androderm; AndroGel; AndroGel Pump; Aveed; Axiron [DSC]; Depo-Testosterone; Fortesta; Jatenzo; Natesto; Striant [DSC]; Testim; Testopel; Vogelxo; Vogelxo Pump; Xyosted

Brand Names: Canada

Andriol [DSC]; Androderm; AndroGel; Axiron [DSC]; Delatestryl; Depo-Testosterone; Natesto; PMS-Testosterone Enhanthate [DSC]; PMS-Testosterone Undecanoate; TARO-Testosterone; TARO-Testosterone Cypionate; Testim

Warning

All products:

- High blood pressure has happened with this drug. Have your blood pressure checked as you have been told by your doctor.
- High blood pressure can raise the chance of heart attack, stroke, or death from heart disease. If you have high blood pressure or heart disease, talk with your doctor.

Testosterone undecanoate injection:

• A very bad lung problem has happened with this drug. Allergic reactions have also happened with this drug. Sometimes, allergic reactions have been life-threatening. These

reactions have happened while this drug was given and right after. These reactions can happen with any dose of this drug.

• You will be watched closely by your doctor for 30 minutes after each dose. Call your doctor right away if you have chest pain, cough or the need to cough, dizziness, passing out, shortness of breath, sweating, or throat tightness.

Skin gel, skin solution:

- Wash the site where the drug was used before it touches anyone else's skin.
- Do not let your skin that the gel or solution was used on touch any children's or women's skin. Cover treated part with clothes. Signs of puberty may happen in children.
- If a woman or child touches the gel, she/he needs to wash the skin with soap and water.

What is this drug used for?

- It is used to treat low testosterone levels.
- It is used in certain children when puberty is delayed.
- It is used to treat breast cancer in women.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

All products:

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you are male and have breast or prostate cancer.
- If you have any of these health problems: Heart disease, kidney disease, or liver disease.

All injection products:

- If you are a woman. Not all injection products are approved for use in women. Talk with your doctor to see if this product may be used in women. If you are a woman using this drug, talk with your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding.
- If the patient is a child. Not all injection products are approved for use in children. Talk with the doctor to see if this product may be used in children.

All products other than injection:

- If you are a woman. This drug is not approved for use in women. This drug may cause harm to an unborn baby if it is taken during pregnancy. If you are a woman using this drug, talk with your doctor if you are pregnant, plan on getting pregnant, or are breastfeeding.
- If the patient is a child. Do not give this drug to a child.

<u>Nose gel:</u>

- If you have problems with swelling of the lining of your nose like Sjogren's syndrome.
- If you have ever had any of these health problems: Broken nose within the past 6 months, nose or sinus problems, nose or sinus surgery, or broken nose that caused the inside of the nose to be crooked (deviated septum).
- If you are using another drug in the nose.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

<u>All products:</u>

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- If you have high blood sugar (diabetes), you will need to watch your blood sugar closely.
- There may be a higher chance of prostate cancer. Talk with the doctor.
- If you have an enlarged prostate, your signs can get worse while you use this drug. Call your doctor if this happens to you.
- If you have sleep apnea, talk with your doctor. Sometimes, sleep apnea has gotten worse in people using testosterone.
- Treatment with this drug may lead to higher cholesterol and triglycerides. The effect of these changes on heart health is not known. Talk with the doctor.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.

- Blood clots have happened with this drug. Tell your doctor if you have ever had a blood clot. Talk with your doctor.
- This drug is an anabolic steroid. Anabolic steroid drugs have been abused and misused before. Anabolic steroid abuse can lead to dependence and very bad health problems. These health problems include heart or blood vessel problems, stroke, liver problems, and mental or mood problems. Talk with the doctor.
- High calcium levels have happened with drugs like this one in some people with cancer. Call your doctor right away if you have signs of high calcium levels like weakness, confusion, feeling tired, headache, upset stomach or throwing up, constipation, or bone pain.
- If you are 65 or older, use this drug with care. You could have more side effects.
- This drug is not approved for treating low testosterone levels caused by getting older. Talk with your doctor.
- Large doses of this drug may affect sperm in males and may affect being able to father a child. If this happens, this may not go back to normal after the drug is stopped. If you have questions, talk with the doctor.

Skin gel, skin solution:

- Tell the doctor right away if a child or woman touches the gel or solution and has any bad effects. In children, these are forceful actions, enlarged sex organs, and early growth of pubic hair. In women, these are a deep voice, change in body hair, or pimples.
- If a pregnant woman touches the gel or solution, call the doctor right away.

<u>Nose gel:</u>

• If you have very bad nose problems like runny nose, stuffy nose, or postnasal drip, or if you have these problems and they do not go away, talk with your doctor. You may need to stop this drug or switch to another product.

<u>Patch:</u>

• The patch may have metal. Take off the patch before an MRI.

Cheek tablet:

• Be sure to inspect your gums where you put this drug on a regular basis. Talk with your doctor.

<u>Testosterone cypionate and testosterone enanthate injection (if given in the muscle):</u>

• If the patient is a child, use this drug with care. The risk of some side effects may be higher in children.

• This drug may affect growth in children and teens in some cases. They may need regular growth checks. Talk with the doctor.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

All products:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Erections (hard penis) that happen often or that last a long time.
- Trouble passing urine, pain when passing urine, passing urine in a weak stream or drips, or passing urine more often.
- Not able to control passing urine.
- New or worse behavior or mood changes like depression or thoughts of suicide.
- Enlarged breasts.
- Breast pain.
- Shortness of breath, a big weight gain, or swelling in the arms or legs.
- Upset stomach or throwing up.
- Trouble breathing when sleeping.
- Feeling sleepy during the day.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- Change in color of skin.
- Change in size or shape of testicles.
- Call your doctor right away if you have signs of a blood clot like chest pain or pressure; coughing up blood; shortness of breath; swelling, warmth, numbness, change of color, or pain in a leg or arm; or trouble speaking or swallowing.

• Liver problems have happened with drugs like this one. Sometimes, this has been deadly. Call your doctor right away if you have signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.

<u>Nose gel:</u>

- Nosebleed.
- Dry nose.
- Nose pain or irritation.
- Runny or stuffy nose.
- Nose scabs.
- Sneezing.

Cheek tablet:

• Gum changes.

Injection products used in females:

• For females, a deep voice, facial hair, pimples, or period changes.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

Capsules:

- Headache.
- Diarrhea.
- Heartburn.
- Burping.

All other products:

- Headache.
- Pimples (acne).
- Diarrhea.
- Emotional ups and downs.
- Feeling tired or weak.
- Trouble sleeping.

• Irritation where this drug is used.

Nose gel:

- Cough.
- Throat irritation.

Cheek tablet:

- Change in taste.
- Bad taste in your mouth.

Patch:

• Back pain.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

<u>Capsules:</u>

• Take this drug with food.

<u>Skin gel, skin solution:</u>

- Do not take this drug by mouth. Use on your skin only.
- Wash your hands before and after use.
- Use this drug at the same time of day.
- Not all products are the same strength. Read and follow label carefully.
- Do not get this drug on other parts of your body or on other people.
- Do not put on the genitals.
- Keep out of your eyes.
- Some products come in pumps. Some products come in packets. If you are using a pump, you will need to prime it before you use it the first time. Prime the pump as you are told in the package insert.
- After putting this drug on, you will need to wait some time before you bathe, shower, or swim. Be sure you know how long you need to wait. Read the package insert for more details.

- Let dry before covering with clothing.
- Avoid fire, flames, or smoking until dry.

<u>Skin gel:</u>

- Put on clean, dry, healthy skin.
- Certain products are to be put on certain parts of the body. Be sure you know where to put this drug. Read the package insert for more details.

Skin solution:

- Put on clean, dry, healthy skin in the armpit using the applicator.
- Do not use your fingers or hand to rub this drug into the skin.
- Change armpits with each dose.
- Allow skin to dry between uses.
- If you use an antiperspirant or deodorant, put on at least 2 minutes before you put on this drug.

Nose gel:

- Do not take this drug by mouth. Use in your nose only. Keep out of your mouth and eyes (may burn).
- If you get this drug on the skin, wash it off right away with soap and water.
- Use this drug at the same time of day.
- Wash your hands before and after use.
- You will need to prime the pump before first use. Do this by turning it upside down and pressing down on the pump 10 times. If any drug comes out during priming, wash down the sink with warm water.
- Blow your nose before use.
- Do not blow your nose or sniff for 1 hour after using this drug.
- Wipe device with a clean tissue. Do not wash.

<u>Patch:</u>

- Do not use patches that are cut or do not look right.
- Put patch on clean, dry, healthy skin on back, belly, thigh, or upper arm.
- Do not put on an area that is bony. Do not put on an area that will have pressure on it for a long time while sleeping or sitting.
- Do not put on the genitals.
- Do not put on skin that is oily, sweats a lot, or has hair on it. The patch may not stick well.

- Put on a new patch at the same time every night. Be sure to take off the old patch before you put on the new one.
- Move the patch site with each new patch. Do not put on the same site for 7 days.
- Do not bathe, shower, or swim for 3 hours after putting on.
- Do not cover the patch with other bandages or tape. If the patch does not stick well, talk with your doctor or pharmacist.
- If your patch falls off before noon, put on a new patch and wear it until you put on a new patch at your normal time.
- If your patch falls off after noon, do not put on a new one. Wait and put on a new patch at your normal time.
- After you take off a skin patch, be sure to fold the sticky sides of the patch to each other. Throw away used patches where children and pets cannot get to them.

Cheek tablet:

- Do not take this drug out of the blister pack until you are ready to take it. Take this drug right away after opening the blister pack. Do not store the removed drug for future use.
- Wash your hands before use.
- Dry your hands and place the tablet in your mouth above the incisor tooth between the upper cheek and gum. Leave the tablet in place until it dissolves.
- Do not chew or swallow.
- Change the side of mouth with each dose.
- Do not take out until it is time for your next dose.
- Make sure drug is still in place after eating, drinking, brushing your teeth, or using mouthwash.
- If the drug does not stick or falls out, follow what your doctor has told you or read the package insert. If you are not sure what to do, talk with your doctor.
- To remove tablet, gently slide it down from the gum toward the tooth to keep from scratching the gum.

All injection products:

- Some products need to be given into the fatty part of the skin. Some products need to be given into a muscle. Talk with the doctor or pharmacist if you are not sure how to use this drug.
- If you will be giving yourself the shot, your doctor or nurse will teach you how to give the shot.

- Wash your hands before use.
- Be sure you know where to give the shot. If you are not sure where to give the shot, talk with the doctor.
- Do not give into skin that is irritated, tender, bruised, red, scaly, hard, scarred, or has stretch marks.
- Do not use if the solution is cloudy, leaking, or has particles.
- This drug is colorless to a faint yellow. Do not use if the solution changes color.
- Throw away needles in a needle/sharp disposal box. Do not reuse needles or other items. When the box is full, follow all local rules for getting rid of it. Talk with a doctor or pharmacist if you have any questions.

What do I do if I miss a dose?

Testosterone undecanoate injection:

• Call your doctor to find out what to do.

All other products:

- Use a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not use 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

All products other than injection:

- Store at room temperature. Do not freeze.
- Store in a dry place. Do not store in a bathroom.

Skin gel, skin solution:

• Protect from heat or open flame.

Cheek tablet:

• Protect from heat.

<u>Patch:</u>

• Store in pouch until ready for use.

All injection products:

• If you need to store this drug at home, talk with your doctor, nurse, or pharmacist about how to store it.

<u>All products:</u>

- Store this drug in a safe place where children cannot see or reach it, and where other people cannot get to it. A locked box or area may help keep this drug safe. Keep all drugs away from pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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