

NATESTO® Important Safety Information for Consumers

INDICATION

What is NATESTO® (testosterone) Nasal Gel?

NATESTO® is a prescription medicine that contains testosterone and is used to treat adult males who have low or no testosterone due to certain medical conditions. Your doctor will test the testosterone level in your blood before you start and while you are using NATESTO®.

NATESTO® should not be used by men with breast cancer or known or suspected prostate cancer. NATESTO® should not be used by women.

It is not known if NATESTO® is safe or effective to treat men who have low testosterone due to aging.

Safety and effectiveness of NATESTO® have not been established in children younger than 18 years old and NATESTO® should not be used by children. NATESTO® use by children may affect bone growth.

NATESTO® is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines. Keep your NATESTO® in a safe place to protect it. Never give your NATESTO® to anyone else, even if they have the same symptoms you have. Selling or giving away this medicine may harm others and is against the law.

IMPORTANT SAFETY INFORMATION

Who should not use NATESTO®?

Do not use NATESTO® if you:

- Are a man who has breast cancer
- Have or might have prostate cancer
- Are pregnant or may become pregnant or are breastfeeding. NATESTO® may harm your unborn or breastfeeding baby.

Talk to your doctor before using NATESTO® if you have any of the above conditions.

What should I tell my doctor before using NATESTO®?

Before using NATESTO®, tell your doctor about all of your medical conditions, including if you:

- Have or have had nose (nasal) or sinus problems or nasal or sinus surgery
- Have had a broken nose (fracture) within the past 6 months

- Have or have had a fracture of your nose that caused the inside of your nose to be crooked (deviated anterior nasal septum)
- Have or have had problems with swelling of the lining of your nose (mucosal inflammatory disorder)
- Have breast cancer
- Have or might have prostate cancer
- Have urinary problems due to an enlarged prostate
- Have heart problems
- Have liver or kidney problems
- Have problems breathing while you sleep (sleep apnea)

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements.

Using NATESTO® with certain other medicines can affect each other. Especially tell your doctor if you take:

- Insulin
- Medicines that decrease blood clotting
- Corticosteroids

How should I use NATESTO®?

- Use NATESTO® exactly as your doctor tells you to. Your doctor will tell you how much NATESTO® to use and when to use it.
- NATESTO® is for use in your nose (intranasally) only.
- NATESTO® can be used with a type of nasal spray called sympathomimetic decongestants such as oxymetazoline. NATESTO® should not be used with other nasal sprays. It is not known if NATESTO® is safe and effective when used with other nasal sprays.

What are the possible side effects of NATESTO®?

NATESTO® may cause serious side effects, including:

- **Nose (nasal) problems.** Signs and symptoms of nasal problems may include runny nose, congestion, sneezing, nosebleed, nasal discomfort, nasal scabbing, or nasal dryness.
- **If you already have enlargement of your prostate gland, your signs and symptoms can get worse while using NATESTO®.** This can include: increased urination at night, trouble starting your urine stream, having to pass urine many times during the day, having an urge

that you have to go to the bathroom right away, having a urine accident, and being unable to pass urine or weak urine flow.

- **Possible increased risk of prostate cancer.** Your doctor should check you for prostate cancer or any other prostate problems before you start and while you use NATESTO®.
- **Changes in red blood cells.**
- **Blood clots in your legs or lungs.** Signs and symptoms of a blood clot in your legs can include leg pain, swelling, or redness. Signs and symptoms of a blood clot in your lungs can include difficulty breathing or chest pain.
- **Possible increased risk of heart attack or stroke.**
- **In large doses, NATESTO® may lower your sperm count.**
- **Possible increased risk of liver problems.** Signs and symptoms of liver problems may include: nausea or vomiting, yellowing of your skin or whites of your eyes, dark urine, or pain on the right side of your stomach area (abdominal pain).
- **Swelling of your ankles, feet, or body, with or without heart failure.** This may cause serious problems for people who have heart, kidney, or liver disease.
- **Enlarged or painful breasts.**
- **Problems breathing while you sleep (sleep apnea).**

Call your doctor right away if you have any of the serious side effects listed above.

The most common side effects of NATESTO® include:

- Increased prostate specific antigen (a test used to screen for prostate cancer)
- Headache
- Runny nose
- Nosebleeds
- Nose pain
- Sore throat, cough
- Upper respiratory infection
- Sinus infection
- Nose scabs

Other side effects include more erections than normal for you or erections that last for a long time.

These are not all the possible side effects of NATESTO®. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information, please see Full Prescribing Information and Patient Information.

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