# Men's Health

### Testosterone: What You Need To Know About The Most Important Male Sex Hormone

(NAPSA)—It's a fact: as men age, their bodies produce less testosterone. However, some men, whose bodies make very little or no testosterone, could have a condition called hypogonadism. The effects of hypogonadism and "Low T" could be a game changer for some men.

Hypogonadism is a relatively common condition in which a man's body doesn't produce enough testosterone.<sup>1</sup> Approximately 40 percent of men over the age of 45 have hypogonadism and "Low T."<sup>2</sup> For men whose bodies aren't able to produce normal levels of testosterone, it may begin to alter their daily life. Signs and symptoms may include: erectile dysfunction, decreased sexual



Men who are concerned about low testosterone should consult with their doctor.

desire, fatigue and loss of energy, depression, loss of certain male physical characteristics and osteoporosis.<sup>3,4</sup> However, the effects of low testosterone needn't be a permanent mainstay—diagnosing low testosterone involves a simple blood test, often conducted in a doctor's office, and once identified, a variety of treatment options are available for hypogonadism.

For men with hypogonadism whose bodies make little or no testosterone, testosterone replacement therapy (TRT) may offer benefits.<sup>5</sup> TRT is available in several forms including topical gels, patches and injections. When choosing a TRT, take the following into consideration:

•Gels. Several preparations are available with different sites of application.<sup>1</sup> With gel application, the body absorbs testosterone through the skin. Gel applications offer effective treatment for male hypogonadism and have low incidences of skin reactions. Packaging flexibility makes gels highly desirable.<sup>3,4</sup>

• Patches. A patch containing testosterone is applied each night to the back, abdomen, upper arm or thigh. Site of the application is rotated to maintain seven-day intervals between applications to the same site to lessen skin reactions.<sup>1</sup>

•**Injections.** Testosterone injections are given in a muscle. Injections can be administered by the patient, family member, nurse or doctor.<sup>1</sup>

If you and your doctor decide that TRT is right for you, then ask about Testosterone Gel (1%), the authorized generic of the Food and Drug Administration (FDA) approved Vogelxo<sup>™</sup> (testosterone) gel 1% for topical use, CIII. Testosterone Gel (1%) is the first and only generic TRT available in three convenient configurations: (unit-dose tubes and packets and a metered dose pump). Vogelxo<sup>15</sup> and Testosterone Gel are a prescription medicine that contains testosterone. Vogelxo<sup>™</sup> and Testosterone Gel are used to treat adult males who have low or no testosterone and with conditions associated with low or no testosterone. It is not known if Vogelxo<sup>™</sup> and Testosterone Gel are safe or effective in children younger than 18 years old. Improper use of Vogelxo<sup>™</sup> or Testosterone Gel may affect bone growth. For more information about Vogelxo<sup>™</sup>, visit www.vogelxo.com.

#### **IMPORTANT SAFETY INFORMATION**

Vogelxo<sup>™</sup> and Testosterone Gel are controlled substances (CIII) because they contain testosterone, which can be a target for people who abuse prescription medicines. Keep your Vogelxo or Testosterone Gel in a safe place to protect it. Never give your Vogelxo or Testosterone Gel to anyone else, even if they have the same symptoms you have. Selling or giving away this medicine may harm others and it is against the law.

What is the most important information I should know about Vogelxo or Testosterone Gel? Early signs and symptoms of puberty have happened in young children who were accidentally exposed to testosterone through contact with men using Vogelxo or Testosterone Gel. Signs and symptoms of early puberty in a child may include:

- enlarged penis or clitoris
- early development of pubic hair
- increased erections or sex drive
- aggressive behavior

It is important that you apply Vogelxo or Testosterone Gel exactly as your healthcare provider tells you to. Vogelxo and Testosterone Gel can transfer from your body to others. Women and children should **avoid contact with the unwashed or unclothed area where Vogelxo or Testosterone Gel has been applied. If a woman or child makes contact with the Vogelxo or Testosterone Gel application area, that area on the woman or child should be washed well with soap and water right away.** 

Stop using Vogelxo or Testosterone Gel and call your healthcare provider right away if you see any signs and symptoms in a child or a woman that may have occurred through accidental exposure to Vogelxo or Testosterone Gel.

- Signs and symptoms of exposure to Vogelxo or Testosterone Gel in children may include: enlarged penis or clitoris; early development of pubic hair; increased erections or sex drive; aggressive behavior
- Signs and symptoms of exposure to Vogelxo or Testosterone Gel in women may include: changes in body hair; a large increase in acne

To lower the risk of transfer of Vogelxo or Testosterone Gel from your body to others, you should follow these important instructions:

- Apply Vogelxo or Testosterone Gel only to the areas of your shoulders and upper arms that will be covered by a short sleeve T-shirt.
- Wash your hands right away with soap and water after applying Vogelxo or Testosterone Gel.
- After the gel has dried, cover the application area with clothing. Keep the area covered until you have washed the application area well or have showered.
- If you expect to have skin-to-skin contact with another person, first wash the application area well with soap and water.

Do not use Vogelxo or Testosterone Gel if you: have breast cancer, or have or might have prostate cancer.

**Vogelxo and Testosterone Gel are not meant for use in women.** Do not use Vogelxo or Testosterone Gel if you are pregnant or may become pregnant or are breastfeeding. Vogelxo and Testosterone Gel may harm your unborn or breastfeeding baby. Women who are pregnant or who may become pregnant should avoid contact with the area of skin where Vogelxo or Testosterone Gel has been applied.

Before you use Vogelxo or Testosterone Gel, tell your healthcare provider if you: 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); or have any other medical conditions.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Vogelxo and Testosterone Gel and certain other medicines you take can affect each other. Especially, tell your healthcare provider if you take: insulin, medicines that decrease blood clotting, or corticosteroids.

It is important that you apply Vogelxo or Testosterone Gel exactly as your healthcare provider tells you to. Your healthcare provider will tell you how much Vogelxo or Testosterone Gel to apply and when to apply it. Your healthcare provider may change your Vogelxo or Testosterone Gel dose. Do not change your Vogelxo or Testosterone Gel dose without talking to your healthcare provider. Vogelxo and Testosterone Gel are to be applied only to the areas of your shoulders and upper arms that will be covered by a short sleeve t-shirt. Do not apply Vogelxo or Testosterone Gel to any other parts of your body such as your penis, scrotum, or stomach area (abdomen).

Vogelxo and Testosterone Gel are flammable until dry. Let Vogelxo or Testosterone Gel dry before smoking or going near an open flame.

#### Vogelxo and Testosterone Gel can cause serious side effects including:

- If you already have enlargement of your prostate gland your signs and symptoms can get worse while using Vogelxo or Testosterone Gel. 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; being unable to pass urine or weak urine flow.
- Possible increased risk of prostate cancer. Your healthcare provider should check you for prostate cancer or any other prostate problems before you start and while you use Vogelxo or Testosterone Gel.
- Blood clots in your legs or lungs. Symptoms of a blood clot in your legs can include leg pain, swelling or redness. Symptoms of a blood clot in your lungs can include difficulty breathing or chest pain.
- In large doses Vogelxo and Testosterone Gel may lower your sperm count.
  Swelling of your ankles, feet, or body, with or without heart failure.
- Enlarged or painful breasts.
- Having problems breathing while you sleep (sleep apnea).
- Call your healthcare provider right away if you have any of the serious side effects listed above.

The most common side effects of Vogelxo and Testosterone Gel include: skin irritation where Vogelxo or Testosterone Gel are applied; increased red blood cell count; headache; and increased blood pressure.

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.

## This safety information is not all-inclusive. For more information, talk to your health care provider and read the Medication Guide for patients and the Full Prescribing Information, including the Boxed Warning regarding the risk of transfer to others. You can also visit www.upsher-smith.com or call 1-888-650-3789.

References:

- 1. Mayo Clinic. Male Hypogonadism. http://www.mayoclinic.org/diseases-conditions/male-hypogonadism/basics/causes/con-20014235?p=1. Accessed May 13, 2014.
- 2. Urology Care Foundation. Low testosterone (hypogonadism). http://www.urologyhealth.org/urology/index.cfm?article=132&display=2. Accessed June 9, 2014.
- 3. Vogelxo [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, Inc; 2014.
- 4. Testim [package insert]. Chesterbrook, PA: Auxilium Pharmaceuticals, Inc; 08/2013.
- 5. National Institute on Aging. Can We Prevent Aging? http://www.nia.nih.gov/health/publication/can-we-prevent-aging. Accessed May 12, 2014.
- Vogelxo is a trademark of Upsher-Smith Laboratories, Inc.