

What You Need to Know About XIAFLEX[®] Treatment for Peyronie's Disease: A Patient Guide

Patients: Keep this guide for important safety information and instructions for your at-home activities.

Healthcare Providers: Review this guide with your patients and give them a copy.

XIAFLEX[®] is a prescription medicine used to treat adult men with Peyronie's disease with an abnormally curved penis and a plaque that can be felt.

What are the serious risks of XIAFLEX[®] treatment?

XIAFLEX[®] can cause serious side effects including:

Penile fracture (corporal rupture) or other serious injury to the penis.

Receiving an injection of XIAFLEX[®] may cause damage to the tubes in your penis called the corpora. After treatment with XIAFLEX[®], one of these tubes may break during an erection. This is called a corporal rupture or penile fracture. This could require surgery to fix the damaged area. Damage to your penis might not get better after corporal rupture.

After treatment, blood vessels in your penis may break, causing blood to collect under the skin (hematoma). This could require a procedure to drain the blood from under the skin. If a hematoma appears, death of skin cells (soft tissue necrosis) may also occur, which could require surgery.

Do not have sex or any other sexual activity between the first and second injections of a treatment cycle with XIAFLEX[®].

Do not have sex or have any other sexual activity for at least **4 weeks** after the second injection of a treatment cycle with XIAFLEX[®] and after any pain and swelling have gone away, or until given permission by your healthcare provider.

When should I call my healthcare provider?

Call your healthcare provider right away if you have any of the following symptoms of penile fracture or other serious injury to the penis:

- **Severe purple bruising and swelling of your penis**
- **Severe pain in your penis**
- A popping sound or sensation in an erect penis
- Sudden loss of the ability to maintain an erection
- Difficulty urinating or blood in the urine

You may report side effects to the FDA at 1-800-FDA-1088 or to the XIAFLEX[®] Medical Information Call Center at 1-800-462-3636.

How can I lower the risks associated with XIAFLEX®?

Before treatment:

- Tell your healthcare provider if you have ever had an allergic reaction to XIAFLEX®.
- Tell your healthcare provider about all the medications you take, especially blood thinner medicines such as aspirin, clopidogrel bisulfate (PLAVIX), prasugrel hydrochloride (EFFIENT) or warfarin sodium (COUMADIN). If you are told to stop taking a blood thinner before your XIAFLEX® injection, your healthcare provider should tell you when to restart the blood thinner.
- Tell your healthcare provider if you have any bleeding problems or if you have other medical conditions.

After treatment:

- Within 24 hours after treatment, your penis may appear bruised and/or swollen and you may have mild-to-moderate penile pain. Ask your healthcare provider if over-the-counter medications are appropriate.
- Do not have sex between the first and second injections of a treatment cycle with XIAFLEX®.
- Do not have sex or have any other sexual activity for at least 4 weeks following the second injection of a treatment cycle with XIAFLEX® and the after any pain and swelling have gone away, or until given permission by your healthcare provider.
- Do the gentle stretching and straightening of your penis at home as shown below.
- Do not use a vacuum erection device during your treatment with XIAFLEX®.
- Avoid situations that may cause you to strain your stomach (abdominal) muscles, such as straining during bowel movements.
- Return to your healthcare provider's office when directed for further injection(s) and/or penile modeling procedures.

What do I need to do at home?

For the 6 weeks after each treatment cycle, you will need to perform the following **gentle penile stretching and straightening** activities. Your doctor will tell you exactly when to start and how long to continue.

1) Penile Stretches (when penis is not erect)

- Grasp the tip of your penis with the fingers of one hand and hold the base of your penis with the fingers of your other hand (see diagram).
- **Gently** pull your penis away from your body to its full length.
- Hold the stretch for 30 seconds.
- Let go and allow your penis to return to its normal, unstretched length.
- Do this stretching three times each day, only when the penis is not erect.

2) Penile Straightening (when penis is erect)

- If you have a spontaneous erection, not related to sexual activity, attempt to straighten your penis by **gently** bending the shaft in the opposite direction of the curve, but not so forcefully so as to produce significant pain or discomfort.
- Hold the penis in this more straightened position for 30 seconds, then let go.
- Do this straightening activity **only one time** each day. If you do not have a spontaneous erection, do not attempt the penile straightening activity.

Side View of Penile Stretching Activity



Top View of Penile Straightening Activity

