

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.

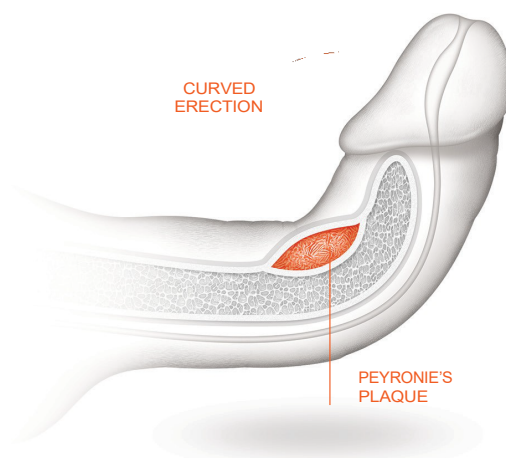
Healthcare Providers: Review this guide with your patients and give them a copy.

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 is Peyronie's disease?

Erectile curvature caused by Peyronie's disease, or PD, is thought to be the result of a problem in the way the body heals after an injury. This scar tissue forms a bump under the skin of the penis. This bump of scar tissue is called a Peyronie's plaque.

This isn't the kind of plaque that can develop in your arteries. If you feel around the inner part of the bend in your penis, you may be able to feel this bump of scar tissue. If the plaque forms on the top of the penis, it will make the erect penis curve up. If the plaque forms on one side of the penis, the erect penis will curve to that side.



What are the serious risks and side effects of XIAFLEX® treatment?

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 (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 XIAFLEX® treatment, blood vessels in your penis may also 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:

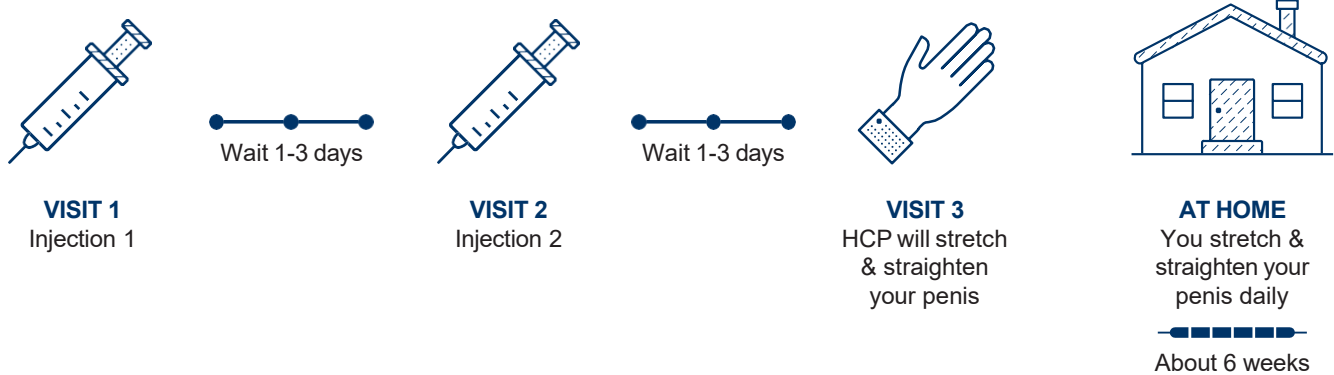
- Tell your healthcare provider if you have ever had an allergic reaction to XIAFLEX®.
- Tell your healthcare provider about **all** the medications you take, especially blood thinner medicines such as aspirin, clopidogrel bisulfate (PLAVIX), prasugrel hydrochloride (EFFIENT) or warfarin sodium (COUMADIN). 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:

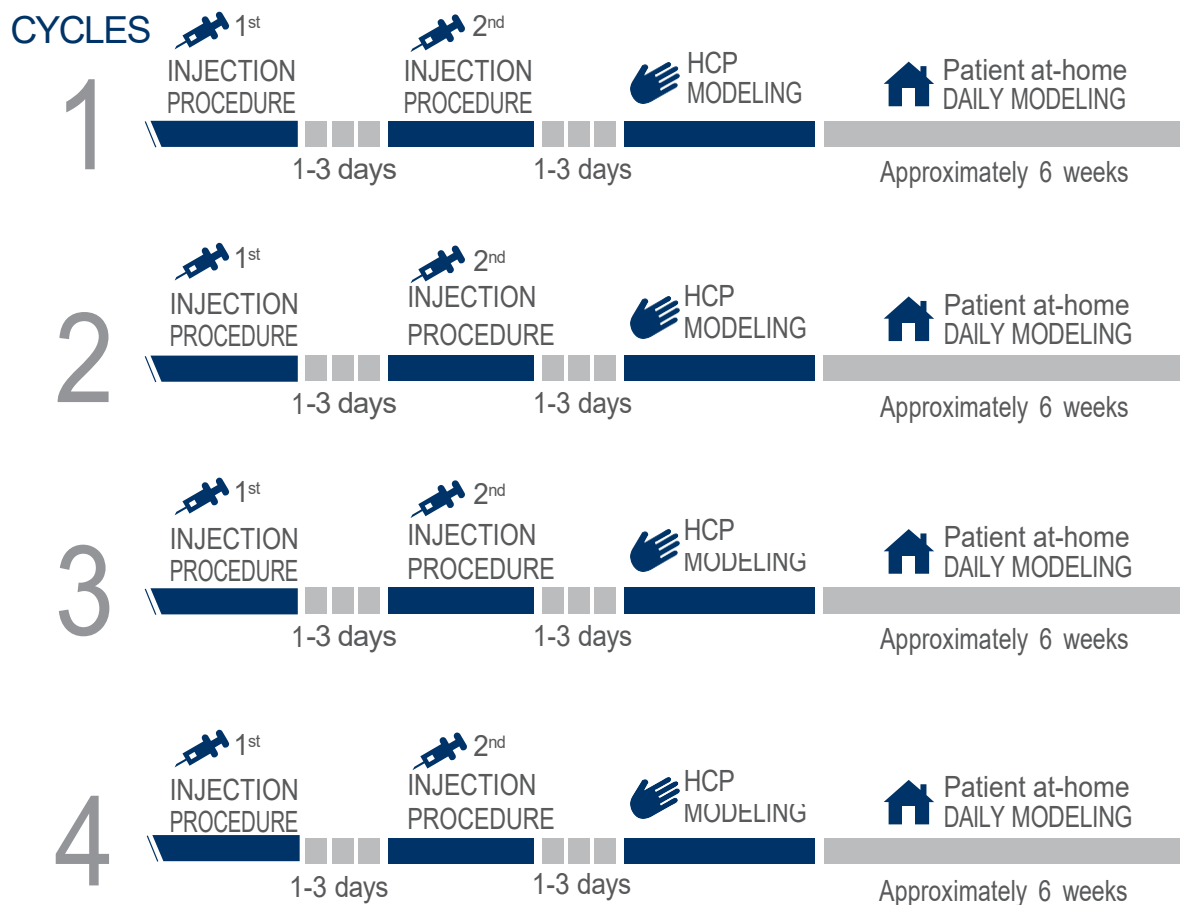
- Within 24 hours after treatment, your penis may appear bruised and/or swollen and you may have mild-to-moderate penile pain. Ask your healthcare provider if over-the-counter medications are appropriate.
- Do not have sex between the first and second injections of a treatment cycle with XIAFLEX®.
- 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 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 is the treatment schedule with XIAFLEX®?

You will book 3 separate office visits for each treatment cycle.



Each treatment cycle consists of 2 XIAFLEX® injection procedures and penile modeling. Each cycle takes approximately 6 weeks to complete.



An entire treatment course of XIAFLEX® consists of up to 4 cycles and takes approximately 24 weeks to complete.

Your role at home.

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

STRETCHING ACTIVITY

Gently stretch your penis **3 times over the course of each day when it is not hard (erect)**.



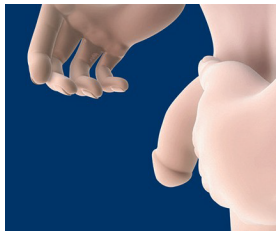
STEP 1

With 1 hand, hold the tip of your penis with your fingers. With your other hand, hold the base of your penis with your fingers.



STEP 2

Gently pull your penis away from your body to its full length and hold the stretch for **30 seconds**.



STEP 3

Let go of the tip of your penis and let your penis return to its normal length.

STRAIGHTENING ACTIVITY

Gently straighten your penis **1 time each day when it is hard (erect) unrelated to sexual activity** (spontaneous erection). This should not cause pain or discomfort.



STEP 1

With 1 hand, hold your erect penis.



STEP 2

With your other hand, gently bend your penis in the opposite direction of the curve.



STEP 3

Hold your penis in this more straightened position for **30 seconds**, then let go.

You must perform both stretching and straightening (modeling activities) at home for a few minutes each day, for 6 weeks after each treatment cycle.