

# GET THE FACTS ABOUT A NONSURGICAL TREATMENT OPTION FOR PEYRONIE'S DISEASE



Actor portrayals.



XIAFLEX<sup>®</sup> is a prescription medicine used to treat adult men with Peyronie's disease who have a "plaque" that can be felt and a curve in their penis greater than 30 degrees when treatment is started.

It is not known if XIAFLEX is safe and effective in children under the age of 18.

## SELECT IMPORTANT SAFETY INFORMATION

**Do not receive XIAFLEX if:**

- the Peyronie's plaque to be treated involves the "tube" that your urine passes through (urethra).
- you are allergic to any collagenase or any of the ingredients in XIAFLEX.

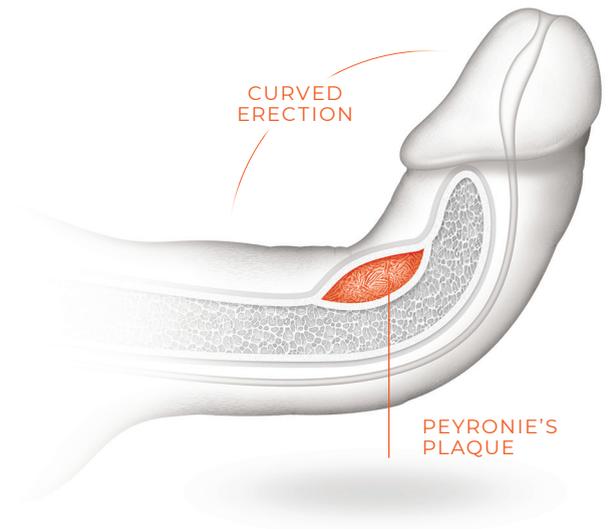
**Please see Important Safety Information on pages 20-23, and click for [full Prescribing Information](#), including [Boxed Warning](#) and [Medication Guide](#).**

**XIAFLEX<sup>®</sup>**  
collagenase clostridium histolyticum injection  
0.9mg

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## WHAT IS PD?

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. The body doesn't properly control how much scar tissue develops, causing too much to build up over time. This scar tissue forms a bump under the skin of the penis. This bump of scar tissue is called a Peyronie's plaque. It's what causes the penis to bend when erect.



## WHAT CAUSES PD?

The exact cause of PD is unknown, but these could likely be contributing factors:



### One or more injuries to the penis

This can occur during athletic activities, an accident, or sex. During vigorous sex especially, the penis can accidentally bend and become injured.



### Genetics

Men with family members who have Peyronie's disease or other related conditions may be more likely to get it. Genetic issues in these men may result in problems healing after an injury.



### Age

Older men may have less firm erections that can bend more easily, which may put them at higher risk for injury.

## WHAT ARE THE SYMPTOMS OF PD?

If you have PD, you may notice these symptoms:

- **A bent erection with or without pain**
- **A bump of scar tissue under the skin** of the penis called a Peyronie's plaque
- Bothered about erection pain, erection appearance, and the impact on intercourse and on frequency of sexual activity

Learn more about the causes and symptoms of PD at [XIAFLEX.com/aboutPD](http://XIAFLEX.com/aboutPD)

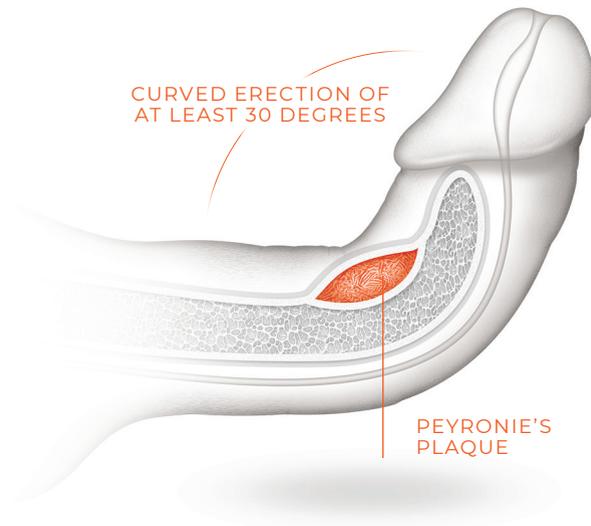


Actor portrayals.

## **ABOUT XIAFLEX<sup>®</sup> (collagenase clostridium histolyticum)**

**XIAFLEX is the only Food and Drug Administration (FDA)-approved nonsurgical treatment option for appropriate adult men with Peyronie's disease.**

Treatment involves a series of injections (1 to 4 treatment cycles about 6 weeks apart), given in-office by a trained urologist. When paired with daily gentle stretching and straightening of the penis, over time XIAFLEX is proven to help reduce erectile curvature. Individual results will vary.



## **WHAT IS XIAFLEX?**

XIAFLEX is a prescription medicine used to treat adult men with Peyronie's disease who have a "plaque" that can be felt and a curve in their penis greater than 30 degrees when treatment is started.

It is not known if XIAFLEX is safe and effective in children under the age of 18.

## **SELECT IMPORTANT SAFETY INFORMATION**

**Do not receive XIAFLEX if:**

- the Peyronie's plaque to be treated involves the "tube" that your urine passes through (urethra).
- you are allergic to collagenase clostridium histolyticum or any of the ingredients in XIAFLEX, or to any other collagenase product. See the end of the Medication Guide for a complete list of ingredients in XIAFLEX.

**Please see Important Safety Information on pages 20-23.**

## ABOUT XIAFLEX® (collagenase clostridium histolyticum) (CONT.)

To be considered for treatment with XIAFLEX, your doctor will need to see if you have the following 2 symptoms:

### A Peyronie's plaque

A bump of scar tissue under the skin of the penis that can be felt

### A bent erection

Bent at least 30 degrees at the start of treatment

**Don't worry about figuring out these things yourself. A urologist or trained urology healthcare professional (HCP) can discuss what your treatment options are depending on your degree of curvature, and also check for the presence of a Peyronie's plaque.**



## SELECT IMPORTANT SAFETY INFORMATION

XIAFLEX can cause serious side effects, including:

- 1. 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 a corporal rupture.
  - After treatment with XIAFLEX, 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, skin and soft tissue necrosis (death of skin cells) may develop in that area, which could require surgery.

Symptoms of corporal rupture or other serious injury to your penis may include:

- a popping sound or sensation in an erect penis
- sudden loss of the ability to maintain an erection
- pain in your penis
- purple bruising and swelling of your penis
- difficulty urinating or blood in the urine

**Call your healthcare provider right away if you have any of the symptoms of corporal rupture or serious injury to the penis listed above.**

**Do not have sex or any other sexual activity between the first and second injections of a treatment cycle.**

**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 has gone away.

XIAFLEX for the treatment of Peyronie's disease is only available through a restricted program called the XIAFLEX Risk Evaluation and Mitigation Strategy (REMS) Program.

*(Continued)*

**Please see Important Safety Information on pages 20-23.**

## THERE ARE 2 EQUALLY IMPORTANT PARTS OF TREATMENT

### PART 1

#### Working with your treatment team

XIAFLEX<sup>®</sup> works to help gradually break down your plaque over 1 to 4 treatment cycles, with about 6 weeks between each cycle.

Book 3 separate office visits for each treatment cycle which consists of:



#### VISIT 1

##### First injection of XIAFLEX

Your urologist will inject XIAFLEX directly into the Peyronie's plaque to help weaken and break it down



Wait 1-3 days



#### VISIT 2

##### Second injection of XIAFLEX



Wait 1-3 days



#### VISIT 3

##### Your urologist will stretch and straighten your penis

You will return to your urologist's office for a manual procedure called *penile modeling*

## SELECT IMPORTANT SAFETY INFORMATION

XIAFLEX can cause serious side effects, including (cont.):

### 2. Hypersensitivity reactions, including anaphylaxis.

Severe allergic reactions can happen in people who receive XIAFLEX, because it contains foreign proteins.

**Call your healthcare provider right away if you have any of these symptoms of an allergic reaction after an injection of XIAFLEX:**

- hives
- chest pain
- swollen face
- low blood pressure
- breathing trouble
- dizziness or fainting

**3. Back pain reactions.** After receiving an injection of XIAFLEX for Peyronie's disease, you may suddenly feel back pain, including severe lower back pain moving to your legs, feet, chest and arms. The back pain may also include spasms and make it hard to walk. These symptoms usually go away in 15 minutes or less, but may last longer.

**Tell your healthcare provider right away if you have sudden back pain, chest pain, or hard time walking after an injection.**

**4. Fainting.** Fainting (passing out) or near fainting can happen in men who receive XIAFLEX, especially if they have severe penile pain.

**If you have dizziness or feel faint after receiving XIAFLEX, lie down until the symptoms go away.**

Please see Important Safety Information on pages 20-23.

## **PART 2** **Your role at home**



### **You will gently stretch and straighten your penis daily**

**For 6 weeks after each treatment cycle with XIAFLEX<sup>®</sup>**, you'll need to take a few minutes each day to do penile modeling activities (refer to pages 14 and 15 for more information).



### **Sexual activity**

You're probably wondering about sex. **For each treatment cycle, do not have sex or engage in any other sexual activity:**

- Between the first and second injections of a treatment cycle
- For at least **4 weeks** after the second injection of each treatment cycle and after any pain and/or swelling have gone away

**This completes 1 of 4 possible treatment cycles. You and your urologist will determine how many cycles are appropriate for you.**

**Work with your treatment team to schedule your appointments for XIAFLEX in advance, and stay in touch with your urologist for any questions or concerns.**

## **After each injection**



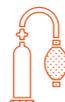
Your penis may be wrapped with a bandage. Your urologist will tell you when to take the bandage off.



It's common to see bruising and swelling, and experience pain after your injections with XIAFLEX at or near the injection site.



Avoid situations that may cause you to strain your stomach (abdominal) muscles, such as straining during bowel movements.



**Do not use any vacuum erection devices during your treatment with XIAFLEX.**

## **SELECT IMPORTANT SAFETY INFORMATION**

**Before receiving XIAFLEX, tell your healthcare provider if you** have had an allergic reaction to a previous XIAFLEX injection, have a bleeding problem, received XIAFLEX for another condition, or 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. Using XIAFLEX with certain other medicines can cause serious side effects. Especially tell your healthcare provider if you take medicines to thin your blood (anticoagulants). 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. Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure.

**Please see Important Safety Information on pages 20-23.**

## 1. 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.

## 2. 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 these 2 penile modeling activities at home for a few minutes each day, for 6 weeks after each treatment cycle.*

## DURING TREATMENT



### Keep track of appointments and your daily penile modeling

Use a calendar app or fill out the appointment reminders on page 18, to help you stay on top of things.



### Perform daily penile modeling activities properly

Your urologist, or a care team member, will show you how to perform these activities (refer to pages 14 and 15 for more information).



### Talk to your partner

It's helpful to discuss how you're feeling with your partner and involve them in the treatment process.



### Stay in touch with your urologist

Be sure to contact your urologist if you have any questions, concerns, or experience any side effects.

## AFTER EACH INJECTION



### You may experience side effects after your injections

It's common to have these reactions at or near the site where XIAFLEX<sup>®</sup> was injected into your penis:

- Swelling
- Bruising
- Pain

**These are not all the possible side effects of XIAFLEX. For more information, ask your urologist.**

Call your urologist right away if you have any of the following symptoms of corporal rupture or serious injury to the penis:

- a popping sound or sensation in an erect penis
- sudden loss of the ability to maintain an erection
- severe pain in your penis
- severe purple bruising and swelling in your penis
- difficulty urinating or blood in the urine

**If you have other questions about what to expect during treatment with XIAFLEX, it's a good idea to ask your urologist.**

## SELECT IMPORTANT SAFETY INFORMATION

### What should I avoid while receiving XIAFLEX?

Avoid situations that may cause you to strain your stomach (abdominal) muscles, such as straining during bowel movements.

**Do not use a vacuum erection device during your treatment with XIAFLEX.**

**Please see Important Safety Information on pages 20-23.**

KEEP TRACK OF YOUR VISITS  
WITH YOUR TREATMENT TEAM

## APPOINTMENTS



**A treatment course consists of up to 4 treatment cycles, approximately 6 weeks apart.**

You and your urologist will determine how many cycles are appropriate for you.

**Consider scheduling all of your appointments for XIAFLEX® in advance.**

### CYCLE 1

1st Injection: \_\_\_\_\_

2nd Injection: \_\_\_\_\_

HCP Modeling: \_\_\_\_\_

### CYCLE 2

1st Injection: \_\_\_\_\_

2nd Injection: \_\_\_\_\_

HCP Modeling: \_\_\_\_\_

### CYCLE 3

1st Injection: \_\_\_\_\_

2nd Injection: \_\_\_\_\_

HCP Modeling: \_\_\_\_\_

### CYCLE 4

1st Injection: \_\_\_\_\_

2nd Injection: \_\_\_\_\_

HCP Modeling: \_\_\_\_\_

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## IMPORTANT SAFETY INFORMATION (CONT.)

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*(Continued)*

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### **What should I avoid while receiving XIAFLEX?**

Avoid situations that may cause you to strain your stomach (abdominal) muscles, such as straining during bowel movements.

**Do not use a vacuum erection device during your treatment with XIAFLEX.**

**XIAFLEX can cause serious side effects, including increased chance of bleeding.** Bleeding or bruising at the injection site can happen in people who receive XIAFLEX. Talk to your healthcare provider if you have a problem with your blood clotting. XIAFLEX may not be right for you.

The most common side effects with XIAFLEX for the treatment of Peyronie's disease include:

- a small collection of blood under the skin at the injection site (hematoma)
- swelling at the injection site or along your penis
- pain or tenderness at the injection site, along your penis and above your penis
- penis bruising
- itching of your penis or scrotum (genitals)
- painful erection
- erection problems (erectile dysfunction)
- changes in the color of the skin of your penis
- blisters at the injection site
- pain with sex
- a lump at the injection site (nodule)

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all of the possible side effects with XIAFLEX. For more information, ask your healthcare provider or pharmacist. You may report side effects to FDA at 1-800-FDA-1088.

**Click for [full Prescribing Information](#), including [Boxed Warning](#) and [Medication Guide](#).**

**~90% of eligible patients paid \$0 out of pocket with the XIAFLEX® Copay Assistance Program.\*†**

\*Restrictions, terms and conditions apply.

Visit [XIAFLEX.com](https://www.xiaflex.com) for details.

†Most eligible patients with commercial insurance plans paid \$0 copay for XIAFLEX. Based on analysis of claims filed November 2017 through April 2020.

**For more information, visit [XIAFLEX.com](https://www.xiaflex.com) or call 877-XIAFLEX (877-942-3539)**

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