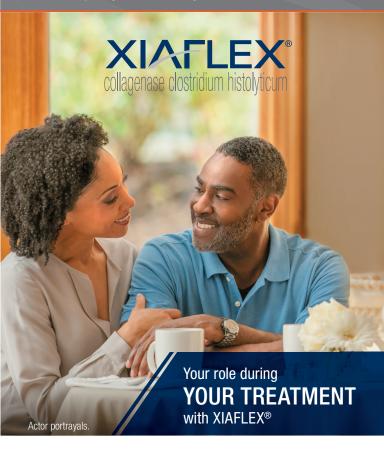
XIAFLEX® is a prescription medicine used to treat adult men with Peyronie's disease who have a "plaque" that can be felt and a curve in their penis greater than 30 degrees when treatment is started.



## AT-HOME PENILE MODELING ACTIVITIES

Visit XIAFLEX.com for videos and other resources.

# IMPORTANT SAFETY INFORMATION FOR XIAFLEX®

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 a corporal rupture.

Please see additional Important Safety Information inside. Please <u>click here</u> for full Prescribing Information, including Boxed Warning and Medication Guide.



For the treatment of Peyronie's disease in adult men who have a "plaque" that can be felt and a curve in their penis greater than 30 degrees when treatment is started.

# A key part of your overall treatment plan with XIAFLEX®

The purpose of this brochure is to help you learn about your role during your treatment with XIAFLEX®.

XIAFLEX® should be injected into the plaque causing your penis to curve by a healthcare provider (HCP) who is trained and experienced in treating adult men with Peyronie's disease.

XIAFLEX® is given as part of a treatment cycle. In each treatment cycle, you will receive an injection of XIAFLEX®, followed by a second injection 1 to 3 days later.

- After each injection of XIAFLEX®, your penis may be wrapped with a bandage. Your healthcare provider will tell you when to take the bandage off
- 1 to 3 days after your second injection of XIAFLEX® in a treatment cycle, you will need to return to your HCP's office for a manual procedure (HCP modeling) that will stretch and help straighten your penis
- 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 2 weeks after the second injection of a treatment cycle with XIAFLEX® and after any pain and swelling has gone away. Your healthcare provider will tell you when you can resume sexual activity after each treatment cycle
- Your healthcare provider will determine how many treatment cycles are appropriate





Stretchina

Straightening

#### Your role at home

Your healthcare provider will show you how to stretch and straighten your penis the right way at home after each treatment cycle. You will need to take a few minutes each day to perform gentle stretching and straightening penile modeling activities on your penis, closely following your healthcare provider's directions.

#### There are 2 types of penile modeling activities:

- The first is a gentle stretching activity to be performed when the penis is not hard (erect)
- The second is a gentle straightening activity, which should be performed when the penis is erect without any sexual activity

Although these activities only take a few minutes, it is important that you follow your healthcare provider's instructions and do them every day for approximately 6 weeks after each treatment cycle.

Read on for details about the penile modeling activities.

# IMPORTANT SAFETY INFORMATION FOR XIAFLEX® (cont)

#### Do not receive XIAFLEX® if you:

- have been told by your healthcare provider that the Peyronie's plaque to be treated involves the "tube" that your urine passes through (urethra)
- 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 additional Important Safety Information on next page and throughout this brochure.



## **Daily stretching**

Gently stretch your penis 3 times a day. Only stretch your penis if your penis is not hard (erect).

- 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.
- Gently pull your penis away from your body to its full length and hold the stretch for 30 seconds
- Let go of the tip of your penis and let your penis return to its normal length

#### STRETCHING ACTIVITY WHEN YOUR PENIS IS NOT ERECT



3X per day

Do your stretching activity 3 times during the course of the day when your penis is not erect.

**Helpful hint #1:** The stretching activity can be done any time of day when you don't have an erection. Establishing a routine may make it easier to remember, so try to do the stretching activity at the same time and place each day. Giving yourself privacy may allow you to feel more comfortable and less rushed.

# IMPORTANT SAFETY INFORMATION FOR XIAFLEX® (cont)

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 a corporal rupture.

Please see additional Important Safety Information on next page and throughout this brochure.

Please <u>click here</u> for full Prescribing Information, including Boxed Warning and Medication Guide.

# Daily straightening

Gently straighten your penis 1 time a day. Only straighten your penis if you have an erection that happens without any sexual activity (spontaneous erection). Bending your penis should not cause any pain or discomfort.

 With 1 hand hold your penis. With your other hand, gently bend your penis in the opposite direction of the curve. Hold the penis in this more straightened position for 30 seconds, then let go

**X**per day

Do your straightening activit once a day when you have a spontaneous erection.



### **STRAIGHTENING ACTIVITY WHEN YOUR PENIS IS ERECT**

**Helpful hint #2:** Spontaneous erections can be more common in the morning, just as you are waking up. This might be a good time for you to do your straightening activity.

Tell your healthcare provider right away if you have trouble stretching or straightening your penis, or if you have pain or other concerns.

# IMPORTANT SAFETY INFORMATION FOR XIAFLEX® (cont)

 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

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.



## Plan ahead for your treatment

1-3

Work with your HCP to schedule all of your treatments with XIAFLEX® in advance to avoid delays.

# INJECTION



1-3

DAYS





PATIENT AT-HOME DAILY MODELING Approximately 6 weeks

## **Appointment Calendar**

#### 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:	/	/	

# CYCLF 2



# CYCLE 3



# CYCLF 4

1st INJECTION	2 <sup>nd</sup> INJECTION	HCP MODELING	PATIENT AT-HOME DAILY MODELING Approximately 6 weeks
	-3 NYS	1-3 DAYS	

Your HCP will determine how many treatment cycles are appropriate.

Please see Important Safety Information on pages 8-10 and throughout this brochure.

Please click here for full Prescribing Information, including Boxed Warning and Medication Guide.

Use this space to record your XIAFLEX® injector's office phone and contact person, for future inquiries.

(	)	-	



## 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.

# IMPORTANT SAFETY INFORMATION FOR XIAFLEX®

#### Do not receive XIAFLEX® if you:

- have been told by your healthcare provider that the Peyronie's plaque to be treated involves the "tube" that your urine passes through (urethra)
- 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®

#### 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

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 2 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. For more information about the XIAFLEX® REMS Program, go to **www.XIAFLEXREMS.com** or call 1-877-942-3539.

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

Before receiving XIAFLEX®, tell your healthcare provider if you have had an allergic reaction to a previous XIAFLEX® injection, or have a bleeding problem or any other medical conditions. Tell your healthcare provider about all the medicines you take, including prescription and non-prescription 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 unsure.

(continued on next page)



# IMPORTANT SAFETY INFORMATION FOR XIAFLEX® (cont)

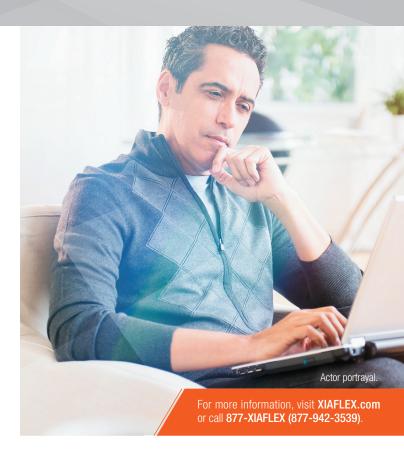
XIAFLEX® can cause serious side effects, including increased chance of bleeding. Bleeding or bruising at the injection site can happen in people who receive XIAFLEX®. Talk to your healthcare provider if you have a problem with your blood clotting. XIAFLEX® may not be right for you.

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<sup>®</sup>. For more information, ask your healthcare provider or pharmacist.



Please read the Medication Guide for XIAFLEX® included in this brochure and keep it for referral while you are being treated with XIAFLEX®.



For more information, visit **XIAFLEX.com** or call **877-XIAFLEX** (877-942-3539).



The information in this brochure should not take the place of talking with your doctor or healthcare provider.

You are encouraged to report negative side effects of prescription drugs. Contact Endo Pharmaceuticals Inc. at 1-800-462-ENDO (3636) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Important Safety Information on pages 8-10 and throughout this brochure.

