

THE UROLOGY GROUP

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XIAFLEX TREATMENT FOR PEYRONIE'S DISEASE

Xiaflex is an injectable medicine used to treat men with Peyronie's disease with a curved penis and a plaque that can be felt. See our Peyronie's Disease webpage for a full discussion of Peyronie's Disease.

Serious risks of Xiaflex

Xiaflex can cause serious damage to the structure of the penis. After treatment, one of the tubes inside the penis could break during an erection, called **penile fracture**. This typically requires surgery. Damage to the penis may not get better after penile fracture, even with surgery. This could lead to permanent inability to have an erection.

Studies have shown 34% improvement in penile curvature in men who underwent treatment with Xiaflex injection compared to 18% improvement in men treated with saline injection.¹ In a study of 832 men, three men had penile fracture.

Go to the Emergency Room if you have the following symptoms of penile fracture or injury:

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

Other risks of Xiaflex

According to the manufacturer², 84% of men had reactions with Xiaflex and 36% had reactions with saline injection. Reactions included blood collection under the skin of the penis (66%), penile swelling (55%), penile pain (45%), penile bruising (15%), discoloration (2%) and pain from the injection (2%). Less than 2% of men in the Xiaflex group had site blisters or itching at the injection site, pain with intercourse or nodule or pain in the low belly. The treatment may not improve the symptoms and could even worsen your symptoms.

It is important that you avoid sexual activity for two weeks after Xiaflex injection and the pain and swelling have gone away.

Tell your provider if you've ever had an allergic reaction to Xiaflex, are on any blood thinner medications [such as aspirin, clopidogrel (Plavix), prasugrel (Effient) or warfarin (Coumadin)] or have a history of bleeding problems or other medical conditions.

Evaluation to see if Xiaflex is right for you

Your provider will likely recommend an injection of medication such as Trimix (prostaglandin E1, phentolamine and papaverine) or Alprostadil (prostaglandin E1) to cause an erection and find the location, direction and amount of curvature. An ultrasound of the penis will likely be done in the same setting to evaluate the structure, function and blood flow of the penis.

Xiaflex injection procedure

Xiaflex injection is performed on a nonerect penis. Your provider will inject the medication into the plaque in the office. One to three days later, a second injection is performed. One to three days after the second injection, your provider will mold the plaque. This is done by applying firm, steady pressure at either end of the plaque to elongate and stretch the penis. This is held for 30 seconds and repeated three times.

You will then need to perform home penile stretching and straightening activities for six weeks.³

The next treatment cycle is then started. Up to four treatment cycles can be used until desired result is reached or the curvature is less than 15%.

Please review "What You Need to Need to Know About Xiaflex Treatment for Peyronie's Disease: A Patient Guide" by Auxilium Pharmaceuticals, Inc., the manufacturer of Xiaflex:

[www.xiaflexrems.com./downloads/RMX-00014-XIAFLEX-REMS-Patient-Guide-\(Patient-Counseling-Tool\)-for-PD-\(5\).pdf](http://www.xiaflexrems.com./downloads/RMX-00014-XIAFLEX-REMS-Patient-Guide-(Patient-Counseling-Tool)-for-PD-(5).pdf)

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References:

1. Gelbard M et al, Clinical efficacy, safety and tolerability of collagenase clostridium histolyticum for the treatment of Peyronie's disease in 2 large double-blind randomized placebo controlled phase 3 studies, *Journal of Urology*, Volume 190, 2013. Pages 199-207.
2. Xiaflex (collagenase clostridium histolyticum) Auxilium Pharmaceuticals, Inc, February 2014. AUA News Update ad, March 2014.
3. "What You Need to Need to Know About Xiaflex Treatment for Peyronie's Disease: A Patient Guide", 2013 Auxilium Pharmaceuticals, Inc., RMX-00014 December.
[www.xiaflexrems.com./downloads/RMX-00014-XIAFLEX-REMS-Patient-Guide-\(Patient-Counseling-Tool\)-for-PD-\(5\).pdf](http://www.xiaflexrems.com./downloads/RMX-00014-XIAFLEX-REMS-Patient-Guide-(Patient-Counseling-Tool)-for-PD-(5).pdf)