

YOUR GUIDE  
TO TREATMENT  
WITH XIAPEX

**XIAPEX**<sup>®</sup> ▽  
collagenase clostridium histolyticum

## LET'S GET THINGS STRAIGHT.

This brochure will guide you through the various stages of your treatment with Xiapex and answer many of the questions you may have.

### *Remember.*

Don't hesitate to ask your doctor about your treatment. This brochure can never replace your doctor's knowledge and guidance.

**XIAPEX**<sup>®</sup>▼  
collagenase clostridium histolyticum

## WHAT IS PEYRONIE'S DISEASE?

Peyronie's disease is named after a French surgeon who described it in the 18th century. It is caused by a development of scar tissue, also called plaque, under the skin of the penis. The plaque causes the penis to bend when erect. Injuries to the penis and/or genetic factors are possible explanations to why this is happening. However, the exact cause of Peyronie's disease is so far unknown.

### IS IT COMMON?

It's not entirely clear how common Peyronie's disease is. It is clear, however, that the occurrence is much higher than once thought. Some studies have estimated that the prevalence – the proportion of a population with a certain disease – is somewhere between 3 and 9 %. But it might be even higher than that, partly due to the fact that men may feel embarrassed to seek help. By now, you've undoubtedly figured out that you're far from alone with having this disease.





## WHAT IS XIAPEX?

Xiapex is a medicine used for the treatment of Peyronie's disease. It contains collagenase clostridium histolyticum, which is a bacterial enzyme that breaks down collagen – one of the body's many building materials. Xiapex helps to weaken and break down the collagen in the plaque that causes your penis to bend. This, along with gentle stretching and straightening of your penis, may help improve your erection curvature.

## WHAT DOES THE TREATMENT INVOLVE?

Xiapex is always administered by a doctor who is experienced in the treatment of urological diseases and who has completed the required training for the use of Xiapex. Your doctor will inject Xiapex directly into the plaque in your penis and thereby help to reduce your penis curvature. Xiapex is given in up to 4 treatment cycles. In each treatment cycle, you will receive 2 injections of Xiapex on separate days, 1 to 3 days apart. Your doctor will determine how many treatment cycles that are appropriate for you. One to 3 days after the second injection, you will need to return to your doctor for a manual procedure that will help stretch the scar tissue that has been weakened. Your doctor will tell you when to come back for this. Be sure to follow your doctor's instructions and wait to resume sexual activities until 2 weeks after the second injection in each treatment cycle and after pain and swelling has gone away.

## YOUR ROLE IS IMPORTANT.

An important part of your treatment with Xiapex involves daily gentle straightening and stretching penis activities. Your doctor may refer to this as "penile modeling". You perform these activities at home after a treatment cycle. Be sure to follow the guidance of your doctor about how to perform these activities, when to begin, and for how long to continue. These activities will help straighten your penis.

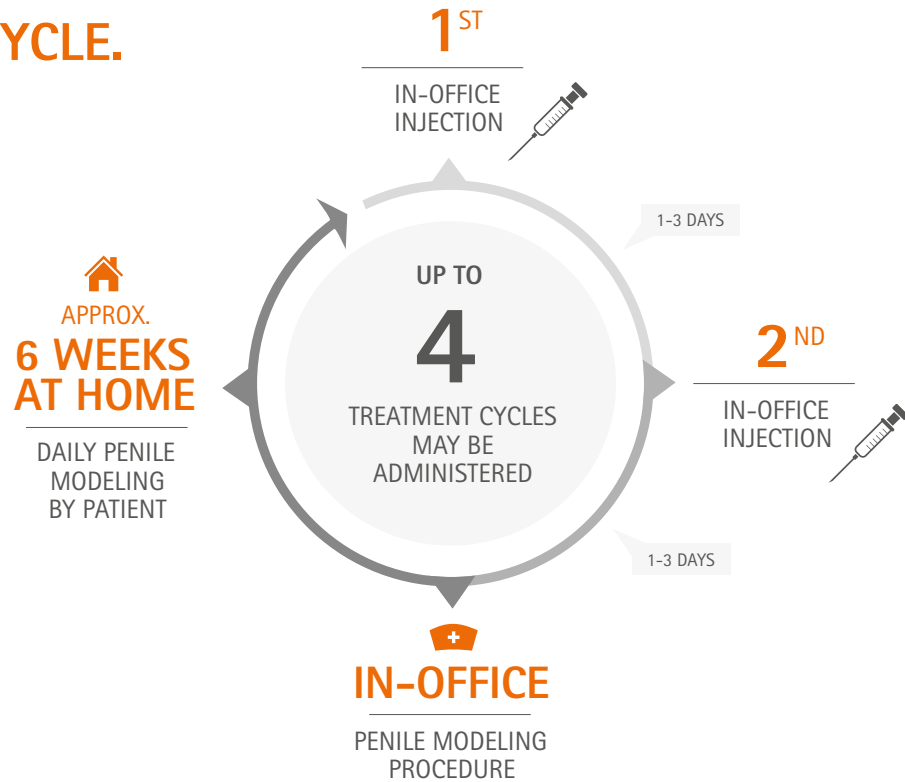
## HOW LONG IS THE TREATMENT?

A full course of Xiapex can take up to 4 treatment cycles. Each cycle (injections and in-office manual straightening and stretching procedures) can take up to 1 week. The interval between each cycle is approximately 6 weeks. During this time your doctor will instruct you to continue the gentle straightening and stretching activities at home. Your doctor will also tell you when to come back if more treatment cycles are needed. A full course of treatment can take up to 24 weeks.



## TREATMENT CYCLE.

10



### 1. PENIS STRETCHING

(when penis is not erect)

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



### 2. PENIS STRAIGHTENING

(when penis is erect)

- During a spontaneous erection, not related to sexual activity, attempt to straighten the 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, and then let go (see picture).
- Do this straightening only one time each day. If no spontaneous erection, do not attempt the penis straightening activity.

11

## WHAT ARE THE SIDE EFFECTS?

Side effects can occur during any treatment, but they vary from person to person. Most side effects experienced by patients treated with Xiapex were mild to moderate and generally disappeared within two weeks.

Note: within 24 hours after treatment, your penis may appear bruised and/or swollen and you may experience mild-to-moderate pain in your penis. Talk to your doctor about what over-the-counter medications that might be appropriate to help lower the pain.

### The following side effects have been seen with Xiapex:

#### Very common side effects

(may affect more than 1 in 10 people):

- bruising or swelling of the penis and pain in the penis
- a small collection of blood under the skin at the injection site

#### Common side effects

(may affect up to 1 in 10 people):

- reactions at the injection site such as presence of a blister, swelling, itching or a solid raised area under the skin
- pain at the injection site and above the penis
- blister or redness/discolouration of the penis
- genital itchiness
- painful erection, painful sex and erectile dysfunction

## ARE THERE ANY RISKS OF SERIOUS SIDE EFFECTS?

Xiapex can cause serious side effects including penile fracture (corporal rupture) or other serious injury to the penis, such as haematoma (a small collection of blood under the skin at the injection site). Call your doctor right away if you experience any of the symptoms of penile fracture or other serious injury to your penis, which are as follows:

- 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

**Also.** Call your doctor right away if you have any of these symptoms of an allergic reaction after an injection of Xiapex:

- hives
- breathing trouble
- swollen face
- chest pain

## REPORTING OF SIDE EFFECTS

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this brochure. By reporting side effects you can help provide more information on the safety of this medicine. You can also report side effects directly via the national reporting system or to the Swedish Orphan Biovitrum Drug Information Center: [medical.info@sobi.com](mailto:medical.info@sobi.com)

## FREQUENTLY ASKED QUESTIONS

### **How soon after treatment can I have sex again?**

Do not have sex or have any other sexual activity for at least 2 weeks after the second injection in each treatment cycle with Xiapex and after any pain and swelling has gone away.

### **Other medicines and Xiapex?**

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Using Xiapex with certain other medicines can cause serious side effects. Especially tell your doctor if you are taking medicines to help control the normal clotting of your blood (known as anti-coagulation medicine).

### **Can I drive and use machines?**

If you experience dizziness, numbness, altered sensation or headaches immediately after an injection of Xiapex you must avoid potentially hazardous tasks such as driving or using machines until these effects have passed or until advised by your doctor.

### **When is Xiapex not recommended?**

If you are you allergic to the active substance in Xiapex (collagenase clostridium histolyticum bacteria) or any of the other substances included in the product, do not undergo treatment with Xiapex. Also, Xiapex is not recommended when treatment of the plaque involves the tube (called the urethra) that your urine passes through. Talk to your doctor about your type of curvature and the suitability of treatment.



**XIAPEX**<sup>®</sup>▼  
collagenase clostridium histolyticum



Swedish Orphan Biovitrum AB  
SE-112 76 Stockholm  
+46 8 697 20 00  
[www.sobi.com](http://www.sobi.com)

005XIA-INT-2015 FEB 2015 RELEVANS.NET

▼ This medicinal product is subject  
to additional monitoring