

YOUR GUIDE
TO TREATMENT
WITH XIAPEX

XIAPEX[®] 
collagenase clostridium histolyticum

LET'S GET THINGS STRAIGHTER.

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.



WHAT IS PEYRONIE'S DISEASE?

Peyronie's disease is named after a French surgeon who discovered it in the 18th century. It is caused by deposition of a lump of collagen protein, also called a 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 happens. However, the exact cause of Peyronie's disease is so far unknown.

IS IT COMMON?

Peyronie's disease is probably much more common than we think. Some research estimates that more than three men in every hundred have this condition, and we know that older men get it more often than younger men. Many men are too embarrassed to get help from their doctors, so it is probably under-reported. But rest assured: you are not alone in having this condition.





WHAT IS XIAPEX?

Xiapex is a medicine used for the treatment of Peyronie's disease. It contains collagenase clostridium histolyticum, a bacterial enzyme that breaks down collagen – the substance that the plaque in the penis is made of. 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, is designed to help reduce the curvature affecting your erection.

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 to start the process of breaking down the plaque which causes your penis to bend. 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 do not have sex or engage in any sexual activity after your first injection and for at least 2 weeks after the second injection in each treatment cycle, and after any pain and swelling has gone away.

YOUR ROLE IS IMPORTANT.

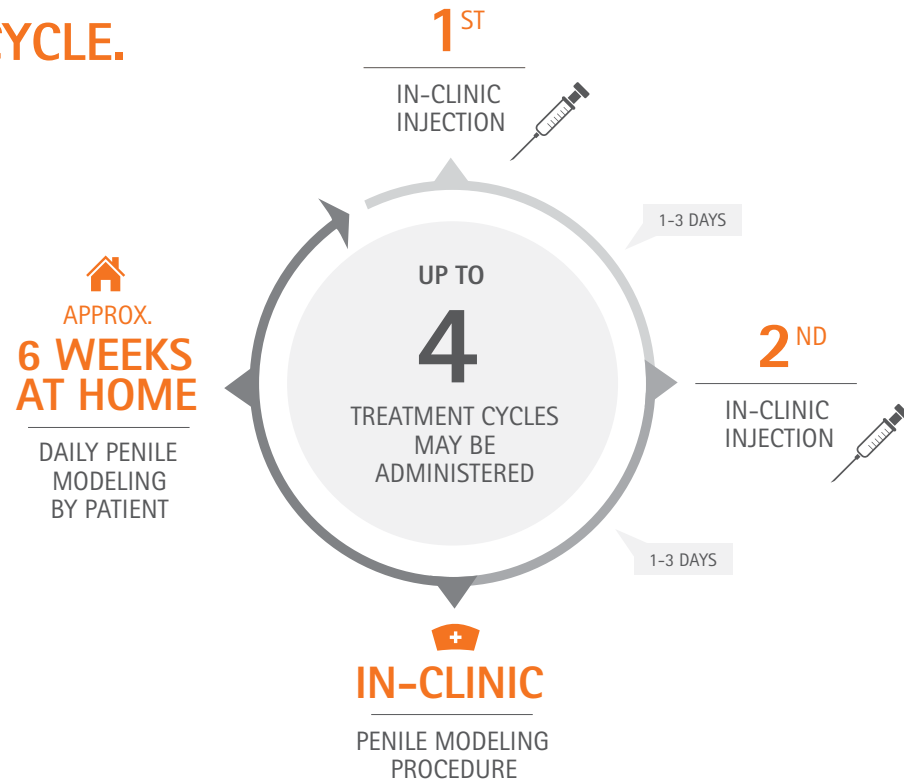
An important part of your treatment with Xiapex involves daily gentle straightening and stretching penis exercises. Your doctor may refer to this as "penile modeling". You perform these exercises at home after a treatment cycle. Be sure to follow the guidance of your doctor about how to perform these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



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.

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 in the clinical trials 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 reduce 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:

- itchy rash
- 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: drugsafety@sobi.com

FREQUENTLY ASKED QUESTIONS

How soon after treatment can I have sex again?

Do not have sex or engage in any sexual activity after your first injection and for at least 2 weeks after the second injection in each treatment cycle, 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 allergic to the active substance in Xiapex (collagenase clostridium histolyticum) 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[®] ▼
collagenase clostridium histolyticum



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▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. In the UK see www.mhra.gov.uk/yellowcard for how to report side effects. In Ireland reporting forms and information can be found at www.hpra.ie