



Your guide to XIAPEX[®] collagenase clostridium histolyticum

A non-surgical treatment for Dupuytren's contracture for adults with a rope-like cord that can be felt beneath the skin (palpable cord)^{1,2}

This guide is for patients who have been prescribed XIAPEX. The information in this booklet is for educational purposes only and is not intended as a substitute for professional medical advice, diagnosis or treatment. Please refer to the *XIAPEX Package Information* for full safety and product information.



Introduction to Dupuytren's disease

The aim of this booklet is to:

- Give you some information about Dupuytren's contracture
- Explain how XIAPEX® works and describe how it would be administered to you
- Answer some questions you may have about your condition and XIAPEX

Dupuytren's disease is a condition which affects the tissue in the palm of the hand and the fingers.³ Dupuytren's disease can cause one or more fingers to become permanently bent inward.³ When this occurs, it is called Dupuytren's contracture. Dupuytren's contracture starts with a build up of cells in the palm of the hand which leads to small lumps.² These lumps are benign (non-cancerous) and usually painless.³

Dupuytren's disease is fairly common, especially among white Europeans.³ More men than women have the condition, which often occurs later in life.³ It is estimated to affect up to 20% of men over 60 years of age, and 20% of women over 80.³ The condition is thought to run in families, though the exact cause(s) remain unknown.³

In some cases of Dupuytren's contracture, the symptoms are mild and no treatment is necessary.³ However, treatment may be required if the normal function of your hand is affected.⁴



What is XIAPEX®?

XIAPEX is the first medicine licensed for adults with Dupuytren's contracture who have a palpable cord.^{1,2}

Treatment begins with two visits to your doctor, one to receive the injection and another during which your doctor will extend your finger to help finish disrupting the cord.¹ If you have Dupuytren's contracture in multiple fingers, your doctor will advise you on which finger should be treated first, as only one cord at a time may be treated.¹

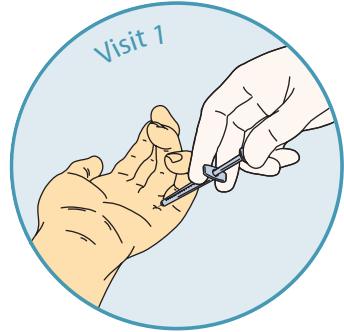
XIAPEX consists of enzymes called collagenases, which break down the cord.² It is injected directly into the cord under your skin so that it reduces the chances of affecting your hand.^{1,2}



What is involved in XIAPEX® treatment?

Visit 1: The injection procedure

Your doctor will provide information as to where your treatment will take place. This is not a surgical procedure, so no incision will be required.¹ Instead, your doctor will use a fine needle to inject directly into the cord.⁵ After your injection, your hand will be wrapped in a gauze dressing.⁵ You will be asked to remain at your treatment centre for 30 minutes to make sure you do not have an allergic reaction to the medicine. If you experience discomfort, please tell your doctor.



Your doctor or nurse will provide you with important instructions to follow when you return home. These may include:

- **Do not** perform strenuous activities with your affected hand⁵
- **Avoid** bending or straightening the fingers of your affected hand¹
- **Keep** your hand elevated as much as possible¹
- **Do not** try to break the cord that received the injection on your own¹
- **Avoid** getting the gauze dressing wet



You should contact your doctor or nurse immediately if you experience any of the following:

- Signs of an allergic reaction, such as wide spread redness or rash, swelling, tightness in the throat or difficulty breathing⁵
- Dizziness or fainting⁵
- Swelling, numbness or tingling in the treated hand⁵
- Signs of infection, such as fever or chills.⁵

You will be asked to return the following day so your doctor can make sure the injection was successful and perform the finger straightening procedure.¹ In some cases, a treated finger may straighten on its own following the injection. It is very important that you do not try to force your finger to straighten.¹ Most people experience swelling, bruising and bleeding around the injected area.¹ Please see the leaflet that comes in the XIAPEX[®] package for a full list of potential side effects.

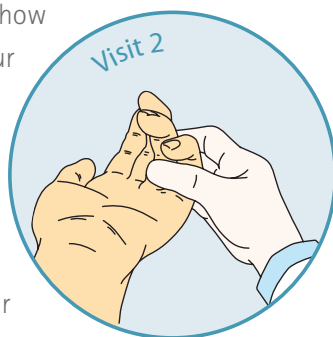


Visit 2: The finger straightening procedure

When you return for your second visit, your doctor will remove the gauze dressing and straighten your finger to break the cord.⁵ As this procedure may cause you some discomfort, your doctor may give you a local anaesthetic.⁵

You may experience some swelling or bruising of the treated hand following this procedure.⁵ It is also possible that your skin may tear during the straightening procedure, especially if your skin is stuck to the cord.⁵ Your doctor will tell you how to look after your skin if this does happen. Your doctor will also recommend the appropriate medicines if you need pain relief.

Before leaving, you will be given a splint to wear on your finger at bedtime. You will also be given some finger exercises to do daily. Your healthcare professional will be able to advise you when it will be safe to begin using your hand fully again.





Follow-up visit

You will be asked to return to your doctor for a follow-up visit around 30 days later.⁵ If necessary, you may receive further treatment, after discussing it with your doctor.⁵ You may also be asked to continue wearing your splint at bedtime for up to 4 months.⁵ If your cord does not break after the first treatment, you can have up to two more treatments, each separated by 4 weeks.¹

XIAPEX® can only be used to treat one cord at a time.¹ If you have more than one joint or other fingers affected with a cord, they will be treated separately.¹



What are the side effects of XIAPEX® treatment?

You should contact your doctor or nurse immediately if you experience any side effects after treatment that concern you.

In clinical trials, most side effects experienced by patients were mild to moderate and generally went away within 2 weeks of the procedure.¹

Please refer to the Package Information for a full list of potential side effects most commonly reported in clinical trials⁵

Very common (affecting more than 1 user in 10) side effects were:

- Reactions at the injection site like bleeding, pain, swelling, tenderness and bruising⁵
- Itching on the hand⁵
- Pain in the hand, wrist or arm⁵
- Swollen or enlarged glands near the elbow or under the arm⁵
- Swelling in the hand or arm.⁵



Common (affecting 1 to 10 users in 100) side effects were:

- Reactions at the injection site like pain, warmth, swelling, blistering, redness and/or rash⁵
- Skin wound at the site of injection⁵
- Pain in the glands near the elbows or under the arm⁵
- Joint swelling and pain⁵
- A burning sensation, partial loss of sensitivity, feeling of "pins and needles" and/or numbness⁵
- Dizziness, headache, nausea⁵
- Increased perspiration.⁵

You may want to discuss any concerns you may have about side effects with your doctor, nurse, or other healthcare professional.

You must inform your doctor if you are breast feeding or are pregnant, or if you have been taking anticoagulants (medicines, such as warfarin and aspirin, that thin the blood) or antibiotics, as XIAPEX[®] treatment may not be appropriate for you.⁵



Will my condition return?

Currently there is no permanent cure for Dupuytren's disease. However, XIAPEX® is an effective treatment option for Dupuytren's contracture in adults with a palpable cord and is generally well tolerated.^{1,2} However, because it does not treat the disease that causes the contracture, a cord may reappear in the future.^{1,6} In this case, your doctor may recommend another course of treatment with XIAPEX or one of several other treatment options.¹

Important information you should consider about XIAPEX

- It is only for adults with a palpable cord¹
- You may want to be accompanied by a friend, family member or caregiver to your appointments. You will be unable to use your hand following the procedures, and you will be unable to drive¹
- You should make sure your doctor knows of any other medicines you are currently taking, including non-prescription medicines⁵
- It is not suitable if you are taking medicine that is used to thin your blood (anticoagulants) including warfarin and clopidogrel.¹ However, low dose aspirin may be suitable (up to 150 mg per day).
- It is not recommended if you have taken tetracycline antibiotics (such as doxycycline) 14 days before your injection¹
- It is not recommended if you are pregnant¹



Some other things you may be wondering about

Q. Can any doctor perform the procedure?

A. Only doctors who are trained in the XIAPEX® injection and extension procedures can perform the treatment.¹ This may mean you will need to see a new doctor for your treatment, or travel to a different clinic or hospital than the one you normally use.

Q. Will I need to have physiotherapy after XIAPEX?

A. You will be expected to do the daily finger exercises recommended by your doctor. Your doctor will let you know of any additional physiotherapy you may need.

Q. What if both of my hands are affected?

A. You will have XIAPEX treatment performed on one cord at a time.¹ You can receive treatment on another cord or the other hand in the future.¹

Q. How soon after treatment can I return to work?

A. Your doctor will be able to advise you on when you can resume normal or strenuous activity following treatment.

Q. How soon after treatment can I return to work?

A. Your doctor will be able to advise you on when you can resume normal or strenuous activity following treatment.

Q. Where can I find more information about Dupuytren's disease?

A. At the NHS Choices website: <http://www.nhs.uk/conditions/Dupuytren's-contracture> and the International Dupuytren's Society.



Important details about your XIAPEX[®] procedure:

Date of **injection**:

Location and time of appointment:

Surgeon/consultant name:

Contact for questions/concerns:

Date and time for **finger extension procedure**:

Date and time of **follow-up visit**:

Other important information:

In the space below, please list any questions you may have for your nurse or surgeon and bring this with you on the day of your injection.

References

1. XIAPEX Summary of Product Characteristics. March 2011.
2. Hurst LC, Badalamente MA, Vincent RH *et al.* *N Engl J Med.* 2009;**361**:968–979.
3. NHS Choices staff. Dupuytren's contracture. Available at: <http://www.nhs.uk/conditions/dupuytren-s-contracture/Pages/Introduction.aspx>. Accessed 13 June 2011.
4. Bayat A, McGrouther DA. *Ann R Coll Surg [Eng].* 2006;**88**:3–8.
5. XIAPEX Package Leaflet. March 2011.
6. Bulstrode NW, Jemec B, Smith PJ *et al.* *J Hand Surg [Am].* 2005;**30**:1021–1025.