

A non-surgical treatment for Dupuytren's contracture^{1*}



Your guide to

XIAPEX[®] ▼

collagenase clostridium histolyticum

The information in this guide 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.

*Xiapex is for adults with a rope-like cord that can be felt beneath the skin of the palm (also known as a palpable cord)¹

▼ This medicinal product is subject to additional monitoring.

You have been diagnosed with Dupuytren's contracture and following discussions with your doctor about treatment options you may be considering Xiapex, a medical procedure that could help to treat your condition.²

The aim of this guide is to:

- Explain how Xiapex works
- Describe how Xiapex would be administered to you

The first symptom of Dupuytren's contracture is usually growth of small lumps of tissue on the palm of the hand. Other symptoms are unusual dimples, thickening of the skin or tenderness around the palm.³

Over time, bands of contracted tissue can develop in the hand, making it difficult for you to straighten your fingers in the same way as before. This process may take months or years.³

The ring finger is most commonly affected by Dupuytren's contracture, followed by the little finger and then the middle finger. One or both hands can be affected.³

As Dupuytren's contracture progresses, the fingers may eventually be pulled into a permanently bent position. This can make it difficult, for example, to wash your face, put on gloves, play the guitar, shake someone's hand, type on a computer keyboard or handle tools.³

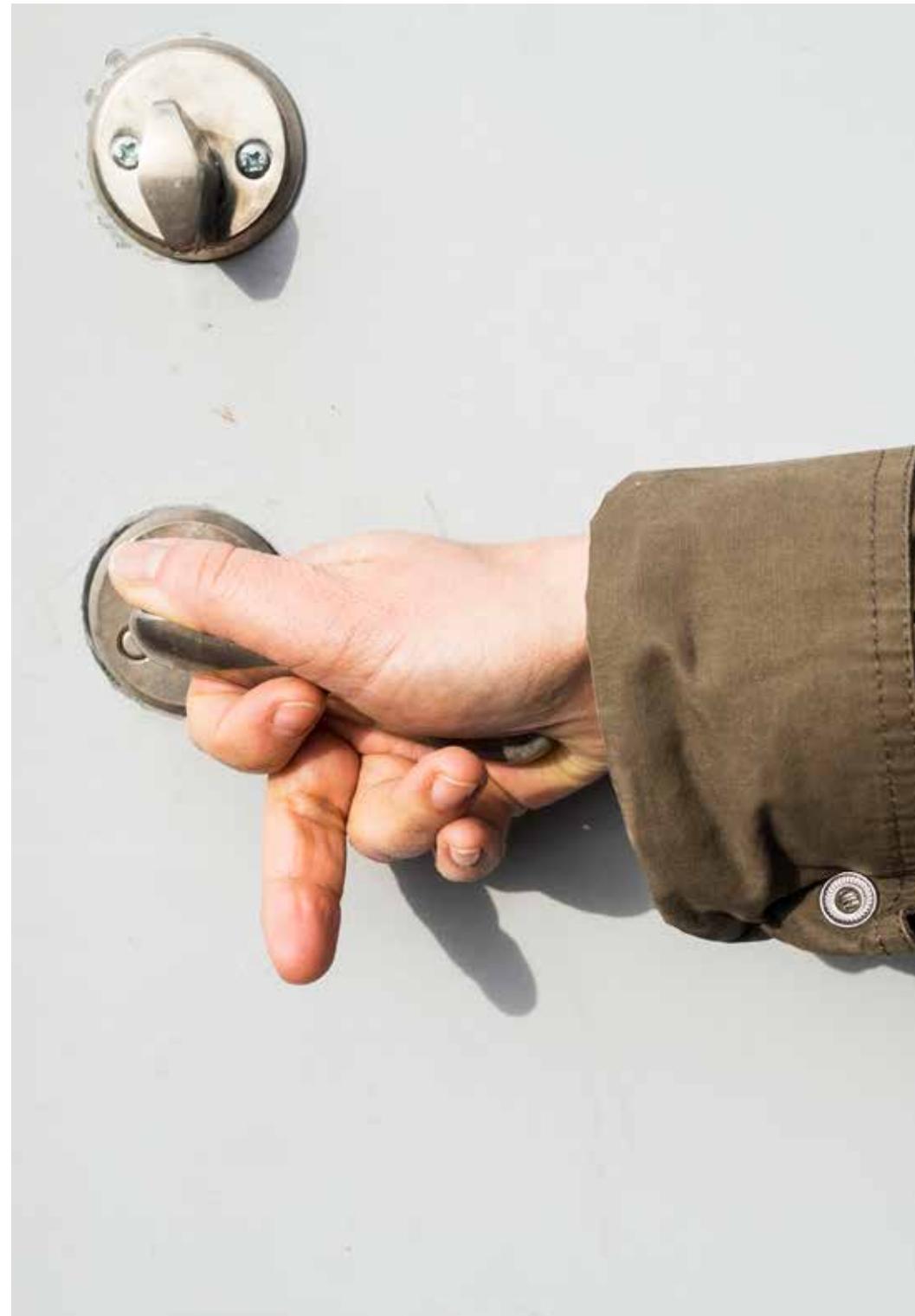


What is Xiapex?

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

The treatment begins with two visits to your doctor, one to receive the injection and another when your doctor will extend your finger.¹

Xiapex works by using enzymes called collagenases, which break down the cord.² Xiapex is injected directly into the cord so that when correctly administered, the risk of complication in other collagen-containing tissues is minimised.^{2,4}



What is involved in Xiapex treatment?

Only doctors who are trained in the Xiapex injection and extension procedures can perform the treatment.¹



Visit 1: The Xiapex injection procedure

- You will go to your doctor's surgery or an outpatient department at your hospital for this injection. No cuts into the skin of your hand will be needed.¹ Instead, your doctor will use a fine needle to inject Xiapex directly into the cord.¹ After your injection, your hand will be wrapped in a gauze dressing.¹
- You will be asked to remain in your doctor's surgery for 30 minutes to make sure you do not have an allergic reaction to the medicine. If you experience discomfort, please tell your doctor.

You will be asked to return the following day for the finger-straightening procedure.¹

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 hand¹
- Avoid flexing or extending the fingers of your affected hand¹
- Keep your hand elevated as much as possible¹
- Do not try to disrupt the cord that received the injection on your own¹
- Avoid getting the gauze dressing wet

Contact your doctor or nurse immediately if you experience any of the following:

- Signs of an allergic reaction, such as skin itching, hives, difficulty breathing or tightness in your chest¹
- Dizziness or fainting¹
- Swelling, numbness or tingling in the treated hand¹
- Signs of infection, such as fever or chills¹

Visit 2: The finger-straightening procedure

- When you return for your second visit the day after, the gauze dressing will be removed. Your doctor will be able to extend your finger as the cord is dissolved by the Xiapex treatment.¹ This procedure may cause some discomfort, so your doctor may give you a local anaesthetic.¹
- You may experience some swelling or bruising of the treated hand following this procedure.¹
- Before leaving, your doctor or nurse will provide you with a splint to wear on your finger at bedtime. You will also be given some finger exercises to perform each day. Your doctor or nurse will be able to advise you when it will be safe to begin using your hand fully again.

In some cases you will be asked to return to your doctor for a follow-up visit 30 days later.¹ If your doctor feels it is necessary, you may receive another full treatment of Xiapex.¹ You will also be asked to continue wearing your splint at bedtime for up to four months.¹ If your cord is not dissolved after the first treatment, you can have up to two more treatments, with a four-week interval between each treatment.¹



What are the side effects of Xiapex treatment?

In clinical trials, most side effects experienced by patients treated with Xiapex were mild to moderate and generally disappeared within two weeks of the procedure.¹

The side effects are listed from very common to uncommon.

Side effects experienced by more than 1 in 10 users:

- Reactions at the injection site, such as bleeding, pain, swelling, tenderness and bruising¹
- Itching on the hand¹
- Pain in the hand, wrist or arm¹
- Swollen or enlarged glands near the elbow or under the arm¹
- Swelling in the hand or arm¹

Side effects experienced by 1–10 out of 100 users:

- Reactions at the injection site, such as pain, warmth, swelling, blistering, redness and/or rash¹
- Skin wound at the injection site¹

- Pain in the glands near the elbows or under the arm¹
- Joint swelling and pain¹
- A burning sensation, partial loss of sensitivity, feeling of 'pins and needles' and/or numbness¹
- Dizziness, headache, nausea¹
- Increased perspiration¹

Uncommon side effects experienced by 1–10 out of 1,000 users:

- Rupture of a tendon, ligament injury¹
- Allergic reaction¹
- Chronic pain¹
- Muscle spasm, weakness and muscle and bone stiffness or discomfort¹

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

You must inform your doctor if you are breastfeeding 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.¹

Will my condition return?

Xiapex is a generally tolerable and effective treatment option for Dupuytren's contracture in adults with a palpable cord.^{1,2} Currently there is no complete cure for Dupuytren's disease. The symptoms can be treated, but regardless of which treatment you receive, Xiapex or any other non-surgical or surgical treatment, the contracture may reappear in the future.^{1,5} In that case, your doctor may recommend another course of treatment with Xiapex.¹

Important information you should consider

- Xiapex is only for adults with a palpable cord¹
- You may want to be accompanied by a friend, family member or caregiver when you go for 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 medicines and vitamins¹
- Xiapex is not suitable if you are taking medicine to thin your blood (anticoagulants), including warfarin and aspirin¹
- Xiapex is not recommended if you have taken tetracycline antibiotics (such as doxycycline) 14 days before your injection¹
- Xiapex treatment is not recommended if you are pregnant¹



Frequently asked questions

Will it hurt?

Some transient pain will occur. You may experience some swelling or bruising of the treated hand following this procedure.¹ Your doctor will tell you how to look after your skin if this happens. Your doctor will also recommend the appropriate medication if you need pain relief.

When can I start using my hand normally again?

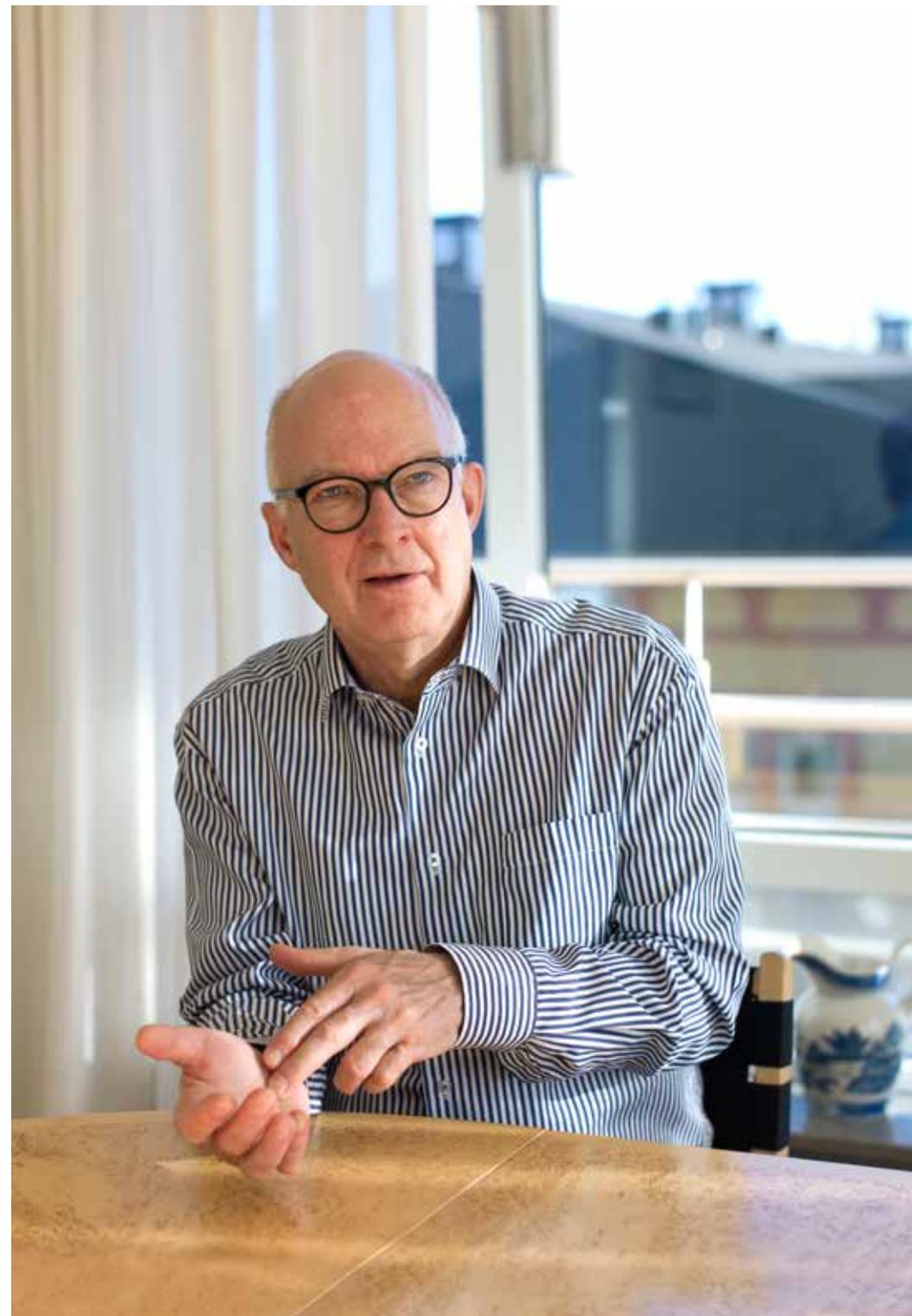
When your finger has been straightened, your doctor will encourage you to resume normal activities but to avoid strain for a certain period.

Will I need physiotherapy after Xiapex?

You will be expected to do the daily finger exercises recommended by your doctor. Your doctor will let you know if you require any additional physiotherapy.

How does this affect my ability to drive a car or other vehicle?

Swelling and pain can impair the function of the treated hand.¹ You should therefore avoid driving, riding a motorbike or operating machinery until you get the go-ahead from your doctor.



Frequently asked questions

How soon after treatment can I return to work?

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

Will the treatment be affected if I take other drugs?

In some cases, yes. If you are taking, or have recently taken, any other medicines, such as antibiotics to treat the infection, blood-thinning agents or non-prescription medications, you should consult your doctor.¹

I have problems with blood clotting/thinning. Can I be treated with Xiapex?

It depends. Consult your doctor.

I am pregnant. Can I be treated with Xiapex?

There are no studies on pregnant women. Treatment should therefore be postponed until after pregnancy.¹ Treatment with Xiapex can be implemented during lactation.¹

When is Xiapex not recommended?

If you are allergic to the active substance in Xiapex (collagenase clostridium histolyticum bacteria) or any of the other substances, do not undergo treatment with Xiapex.¹



Important details about your Xiapex procedure:

Date of Xiapex injection: _____

Location and time of appointment: _____

Surgeon/consultant name: _____

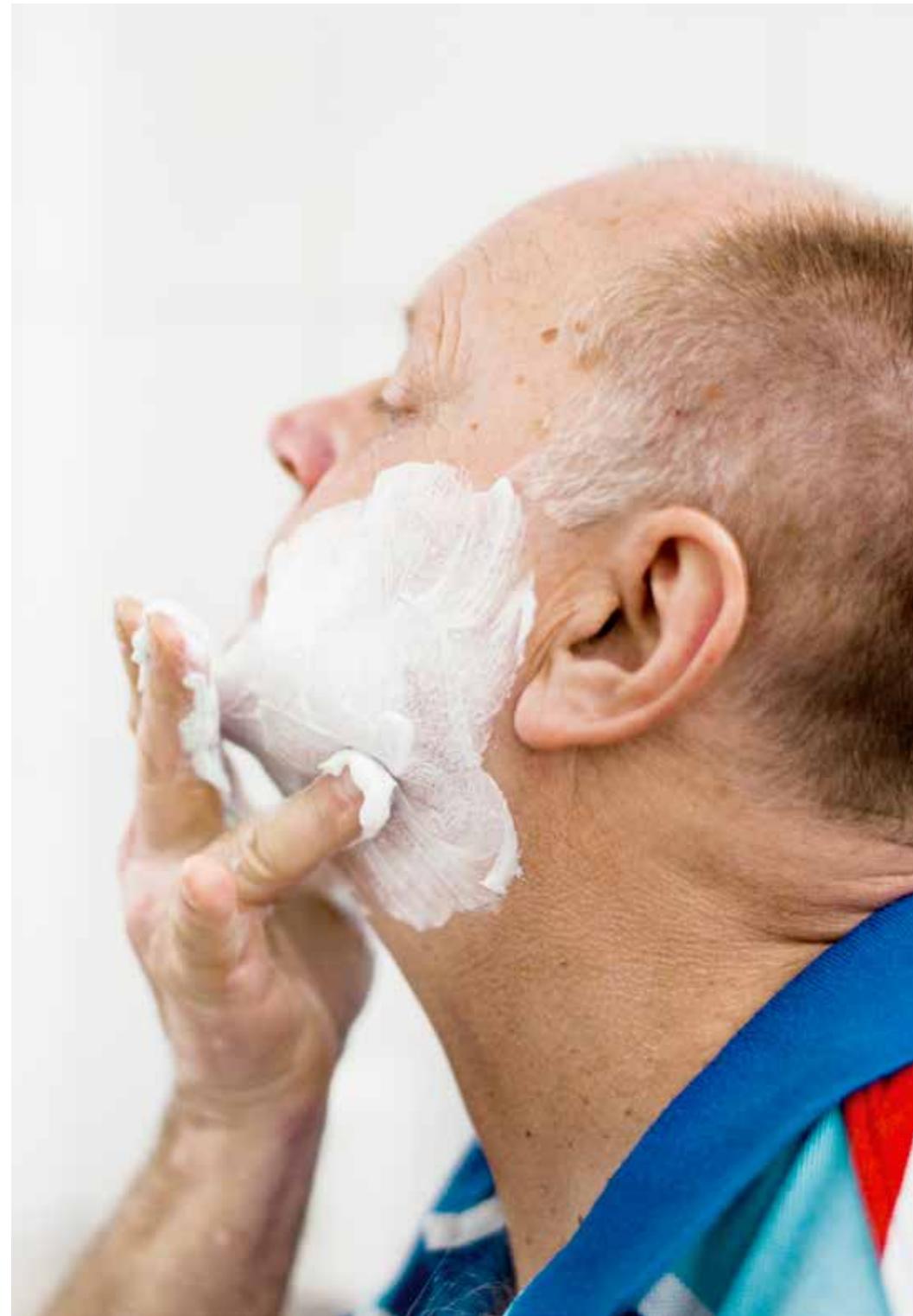
Contact for questions/concerns: _____

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. Nov 2013.
2. Hurst LC et al. N Engl J Med 2009; 361(10):968-79.
3. NHS Choices website. Dupuytren's contracture. Available at: www.nhs.uk/Conditions/Dupuytren's-contracture. Accessed December 2013.
4. Thomas A et al. Ther Clin Risk Manag 2010; 6:557-72.
5. Bulstrode NW et al. J Hand Surg Am 2005; 30(5):1021-5.



SE-112 76 Stockholm Sweden

XIAPEX[®]
collagenase clostridium histolyticum