

Patient Guide

Understanding Dupuytren's contracture and treatment with XIAFLEX® (collagenase clostridium histolyticum)

This booklet is intended as an education resource for patients who have been diagnosed with Dupuytren's contracture and been prescribed XIAFLEX® treatment.



XIAFLEX®
collagenase clostridium histolyticum

Dupuytren's contracture: the facts

What exactly is Dupuytren's contracture, and what can you do to treat it?

Dupuytren's (pronounced, "Doo puh trenz") contracture is a progressive hand condition that affects the palm and the fingers.

It's not easy to say, but if you look closely, it can be easy to spot. The layer of tissue just under the skin can develop an abnormal build-up of something called collagen, a protein that's seen in tissues throughout your body. In Dupuytren's contracture, this collagen builds up and over time can thicken into a rope-like cord in your palm. These changes become more noticeable as fingers begin to curl and cannot be straightened. Some mistake this for arthritis or other conditions.

What **real patients** are saying:



"It started at the age of 45 when I began to notice "bands" in the palms of my hands."

Bob, age 56, engineer
Newcastle, New South Wales

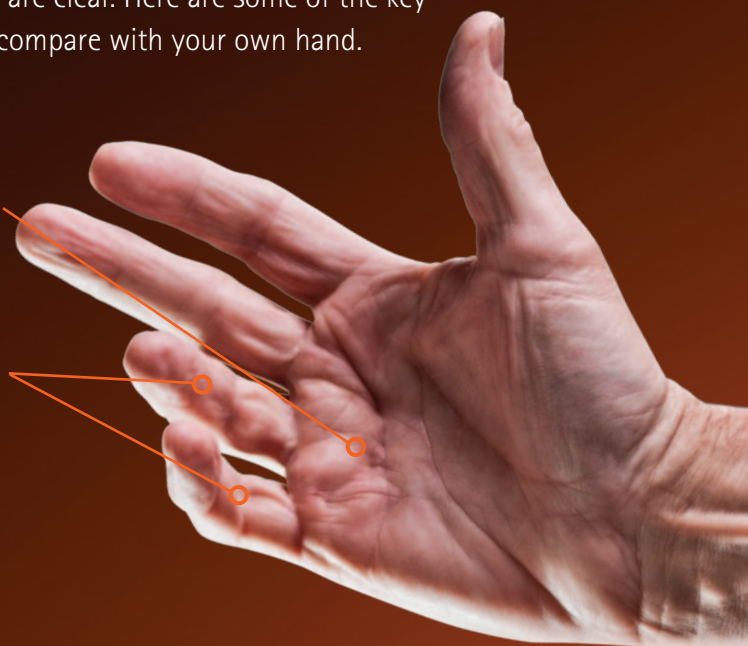
XIAFLEX® is used for the treatment of Dupuytren's contracture in adult patients with a palpable cord.

Signs to look for

Every hand is unique, but the signs that you may have Dupuytren's contracture are clear. Here are some of the key signs to look for and to compare with your own hand.

Rope-like cord forms in the palm

One or more fingers pull inward



What happens when the cord tightens?

As Dupuytren's contracture progresses over time, the cord can extend from the palm into the finger. Gradually, the cord pulls the finger down toward the palm. If the cord tightens, these fingers will bend toward the palm so you cannot straighten them. This bend is called a "contracture," which is why it's called Dupuytren's contracture. Besides causing contracture, the tightening of the Dupuytren's cord can reduce your finger's range of motion (how much you can move or straighten them). Dupuytren's contracture progresses at a different pace in different people. Once a doctor can feel the Dupuytren's cord, it is referred to as a "palpable cord."

For adults dealing with Dupuytren's contracture with a palpable cord, XIAFLEX® (collagenase clostridium histolyticum) is a TGA-approved treatment option.

One that may not require surgery

About XIAFLEX®

XIAFLEX® is a TGA-approved nonsurgical treatment option for adults with Dupuytren's contracture with a palpable cord.

There's no cure for Dupuytren's contracture, but there are effective treatment options. Your hand specialist can help explain your options. You received this patient guide, because your hand specialist has prescribed XIAFLEX® to you.

What **real patients** are saying:

"When I found out there was another alternative that was not invasive, but an injection, I thought, my gosh, maybe this is something that can improve my hand."

Ken, age 67, retired journalist
Melbourne, Victoria



How does XIAFLEX® work?

XIAFLEX® contains a mixture of enzymes that are injected directly into a Dupuytren's cord. These enzymes help break down the cord and allow the finger to straighten.

XIAFLEX® is injected into the Dupuytren's cord by a doctor experienced in procedures of the hand and the surgical treatment of patients with Dupuytren's contracture. XIAFLEX® should only be used by an approved practitioner who will be able to display (or show you) such an authorisation. One day later, the doctor will extend the injected finger to help break the cord if necessary. No incisions are required to administer XIAFLEX®. Injections and finger extension procedures may be administered up to 3 times per cord at approximately 4-week intervals.



1. Your doctor will inject XIAFLEX®

- Your doctor will inject XIAFLEX® into the cord that is causing your finger to bend—up to 3 injections per cord may be given at approximately 30-day intervals if necessary
- If your cord to be treated is attached to the skin, you are at higher risk of the skin splitting or tearing during the finger extension procedure following the injection with Xiaflex. This will usually be treated by applying a dressing. In severe cases a skin graft may be necessary.
- After the injection of XIAFLEX®, your affected hand will be wrapped with a bandage and you will be observed for at least 20 minutes to ensure you are not experiencing an allergic reaction.
- You should limit moving and using the treated finger after the injection. Do not try to straighten the treated finger yourself
- Keep the injected hand elevated until bedtime



2. Your doctor may need to extend your finger

- Return to your doctor's office for a follow-up visit as directed about 24 hours after your XIAFLEX® injection
- If the cord is still intact, your doctor may need to extend the treated finger to "break" the cord in order to straighten your finger
- You may hear a popping or cracking sound as the cord breaks, similar to knuckles cracking. This is normal
- Your doctor will provide a splint to wear on the treated hand



3. Your doctor will check on your progress

- Return to your doctor about 30 days after the procedure to check on your progress



- Perform finger exercises each day, as instructed by your doctor
- Wear the splint as instructed by your doctor at bedtime to keep your finger straight
- Follow your doctor's instructions about when you can resume your normal activities with the injected hand

IMPORTANT SAFETY INFORMATION

XIAFLEX® can cause serious side effects including tendon rupture (break), ligament damage, nerve injury or other serious injury of the hand, or allergic reaction.

Call your doctor right away if you have difficulty bending your injected finger after the swelling goes down, pain, tingling, numbness, or problems using your treated hand. If any of the following signs of allergy occur, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- widespread redness or rash
- swelling
- tightness in the throat or difficulty breathing.

These side effects are rare.

It's important to tell your doctor about a prior allergic reaction to XIAFLEX®, or if you have a bleeding problem or use a blood thinner.

Common side effects include hand swelling, bruising, injection site reaction or bleeding, and pain.

Please see additional Important Safety Information on the following page.

XIAFLEX® is used for the treatment of Dupuytren's contracture in adult patients with a palpable cord. Over time, the thickening of this cord in your hand can cause one or more fingers to bend towards your palm, so that you cannot straighten them. XIAFLEX® helps to break down the cord that is causing the finger to be bent. XIAFLEX® should be injected into the cord by a healthcare provider who is experienced in injection procedures of the hand and in treating people with Dupuytren's contracture. XIAFLEX® should only be used by an approved practitioner who will be able to present their certification upon request.

IMPORTANT SAFETY INFORMATION

XIAFLEX® can cause serious side effects, including:

- Tendon or ligament damage. Receiving an injection of XIAFLEX® may cause damage to a tendon or ligament in your hand and cause it to break or weaken. This could require surgery to fix the damaged tendon or ligament. Your doctor will take care to avoid injecting into tendons, nerves or blood vessels. Call your healthcare provider right away if you have trouble bending your injected finger (towards the wrist) after the swelling goes down or you have problems using your treated hand after your follow-up visit.
- Nerve injury or other serious injury of the hand. Call your healthcare provider if you get numbness, tingling, or increased pain in your treated finger or hand after your injection or after your follow-up visit.
- Allergic reactions. Allergic reactions can happen in people who have received an injection of XIAFLEX® because it contains foreign proteins. Call your healthcare provider right away, or visit the closest Accident and Emergency, if you have any of these symptoms of an allergic reaction after an injection of XIAFLEX®:
 - hives
 - swollen face
 - breathing trouble
 - chest pain

Before receiving XIAFLEX[®], tell your healthcare provider if you have had an allergic reaction to a previous XIAFLEX[®] injection, or have a bleeding problem or any other medical conditions. Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Be sure to tell them if you use blood thinners such as aspirin, clopidogrel (e.g., Plavix[®]), prasugrel hydrochloride (Effient[®]), or warfarin sodium.

Please let your healthcare provider know if you are taking or have been taking any other medicines, especially tetracyclines.

Very common side effects with XIAFLEX[®] include:

- reactions at the injection site like bleeding, pain, swelling, tenderness and bruising
- itching in the hand
- feeling of pain in the hand, wrist or arm
- swollen or enlarged glands near the elbow or under the arm
- swelling in the hand or arm

Please review the enclosed Consumer Medicines Information for further safety information in the back pocket of this brochure.

To report a side effect, please contact your doctor or Actelion Pharmaceuticals Australia Drug Safety on 02 9486 4600 or drugsafetyau@actelion.com

What **real patients** are saying:



"I don't give up on anything, and I was very happy when my doctor told me there was an alternative to surgery."

Margaret, age 61, retired teacher
Gold Coast, Queensland

XIAFLEX[®]
collagenase clostridium histolyticum

XIAFLEX® is a registered trademark of
Auxilium International Holdings, Inc.

Actelion Pharmaceuticals Australia Pty Ltd.
ACN 097 278 512.
P.O Box 372
Frenchs Forest NSW 1640.

Date of Preparation: July 2013
2013/07/XFX/02

Please see enclosed Consumer Medicines Information in back pocket.

This booklet is provided as a patient service by Actelion Pharmaceuticals Australia Pty Limited. Actelion Pharmaceuticals Australia Pty Limited is the sponsor of XIAFLEX® (Collagenase Clostridium histolyticum) in Australia.

This booklet is intended as an education resource for patients who have been diagnosed with Dupuytren's contracture and been prescribed XIAFLEX® treatment by the specialist. It is not intended as a substitute for guidance and instructions by a qualified medical doctor or healthcare professional, nor is it considered a comprehensive and exhaustive source of information of Dupuytren's disease and its treatments. The publisher recommends that medical advice is sought for all queries and concerns to the condition Dupuytren's disease and/or any treatments for such.

