

**MEDICATION GUIDE**  
**XIAFLEX™ (Zī a flex)**  
**(collagenase clostridium histolyticum)**

Read this Medication Guide before you receive XIAFLEX and each time you get an injection. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or treatment.

**What is the most important information I should know about XIAFLEX?**

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. 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 take XIAFLEX because it contains foreign proteins.

Call your healthcare provider right away if you have any of these symptoms of an allergic reaction after an injection of XIAFLEX:

- hives
- swollen face
- breathing trouble
- chest pain

**What is XIAFLEX?**

XIAFLEX is a prescription medicine used to treat adults with Dupuytren's contracture when a "cord" can be felt.

In people with Dupuytren's contracture, there is thickening of the skin and tissue in the palm of your hand that is not normal. Over time, this thickened tissue can form a cord in your palm. This causes one or more of your fingers to bend toward the palm, so you can not straighten them.

XIAFLEX should be injected into a cord by a healthcare provider who is skilled in injection procedures of the hand and treating people with Dupuytren's contracture. The proteins in XIAFLEX help to "break" the cord of tissue that is causing the finger to be bent.

It is not known if XIAFLEX is safe and effective in children under the age of 18.

## **What should I tell my healthcare provider before starting treatment with XIAFLEX?**

XIAFLEX may not be right for you. Before receiving XIAFLEX, tell your healthcare provider if you:

- have had an allergic reaction to a previous XIAFLEX injection.
- have a bleeding problem.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if XIAFLEX will harm your unborn baby.
- are breastfeeding. It is not known if XIAFLEX passes into your breast-milk. Talk to healthcare provider about the best way to feed your baby if you receive XIAFLEX.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you use:

- a blood thinner medicine such as aspirin, clopidogrel (PLAVIX®), prasugrel hydrochloride (EFFIENT®), or warfarin sodium (COUMADIN®). If you are told to stop taking a blood thinner before your XIAFLEX injection, your healthcare provider should tell you when to restart the blood thinner.

## **How will I receive XIAFLEX?**

- Your healthcare provider will inject XIAFLEX into the cord that is causing your finger to bend.
- After an injection of XIAFLEX, your affected hand will be wrapped with a bandage. You should limit moving and using the treated finger after the injection.
  - Do not bend or straighten the fingers of the injected hand until your healthcare provider says it is okay. This will help prevent the medicine from leaking out of the cord.
  - Do not try to straighten the treated finger yourself.
- Keep the injected hand elevated until bedtime.
- Call your healthcare provider right away if you have
  - signs of infection after your injection, such as fever, chills, increased redness, or swelling
  - numbness or tingling in the treated finger
  - trouble bending the injected finger after the swelling goes down
- Return to your healthcare provider's office as directed on the day after your injection. During this first follow-up visit, if you still have the cord, your healthcare provider may try to extend the treated finger to "break" the cord and try to straighten your finger.

- Your healthcare provider will provide you with a splint to wear on the treated finger. Wear the splint as instructed by your healthcare provider at bedtime to keep your finger straight.
- Do finger exercises each day, as instructed by your healthcare provider.
- Follow your healthcare provider's instructions about when you can start doing your normal activities with the injected hand.

### **What are the possible side effects of XIAFLEX?**

**XIAFLEX can cause serious side effects. See “What is the most important information I should know about XIAFLEX?”.**

#### **Common side effects with XIAFLEX include:**

- swelling of the injection site or the hand
- bleeding or bruising at the injection site
- pain or tenderness of the injection site or the hand
- swelling of the lymph nodes (glands) in the elbow or underarm
- itching
- breaks in the skin
- redness or warmth of the skin
- pain in the underarm

These are not all of the possible side effects with XIAFLEX. Tell your healthcare provider about any side effect that bothers you or does not go away.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

### **General information about XIAFLEX**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about XIAFLEX. If you would like more information, talk to your healthcare provider. You can ask your healthcare provider for information about XIAFLEX that is written for health professionals. For more information visit [www.XIAFLEX.com](http://www.XIAFLEX.com) or call 1-877-663-0412.

### **What are the ingredients in XIAFLEX?**

Active ingredient: collagenase clostridium histolyticum.

Ingredients: hydrochloric acid, sucrose, and tromethamine. The diluent contains: calcium chloride dihydrate in 0.9% sodium chloride.

Manufactured and distributed by:  
Auxilium Pharmaceuticals, Inc.  
Malvern, PA 19355  
USA

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

US License No. 1816

PL-1109-001.a

## HEALTHCARE PROVIDER INFORMATION

DIAGNOSIS: Dupuytren's contracture ICD-9 728.6  Yes  No

Physician Name  Physician Specialty

Facility/Practice Name  Contact Person

Address

City  State  Zip

Fax  Phone  Phone Type  Main  Direct  Mobile

Alternate Phone  E-mail

XIAFLEX Xperience ID#  Product

Number of Cords: **Right Hand** # of MP joints to treat  # of PIP joints to treat  **Left Hand** # of MP joints to treat  # of PIP joints to treat  **Note:** Each course of treatment per joint can be up to 3 injections.

Insurance: Patient is uninsured (no third-party or private insurance)  YES  NO

## PHYSICIAN CERTIFICATION

My signature below certifies (1) that the person named on this form is my patient and that XIAFLEX received in response to this application is only for the use of the patient named on this form; (2) that this medication will not be offered for sale, trade, or barter; (3) that no claim for reimbursement of either XIAFLEX or related medical procedures and services will be submitted to Medicare, Medicaid, or any third party; (4) that XIAFLEX will not be returned for credit; (5) that Auxilium Pharmaceuticals has the right to contact my patient directly to confirm receipt of XIAFLEX, and to revise, change, or terminate this program at any time; (6) that to the best of my knowledge my patient meets Auxilium's criteria for the XIAFLEX Patient Assistance Program; and (7) that the information provided in this application is complete and accurate.

Physician Signature  Date

## PATIENT INFORMATION

Patient Name  Date of Birth  Social Security Number

Address  City

State  Zip Code  Phone Number

Total Household Income  Total # of Household Dependents  Alternate Phone Number

## ELIGIBILITY AND TREATMENT INFORMATION

Residency: US resident or permanent citizen  Yes  No

Income documentation attached (1040, 1040EZ, SSI Letter, SSDI, IRS-4506-T, Notarized Letter)  Yes  No

## PATIENT CERTIFICATION AND CONSENT

I would like to receive XIAFLEX at no charge under the XIAFLEX Patient Assistance Program. I understand that all the information I provide in connection with this application will be used to determine my eligibility to participate in the XIAFLEX Patient Assistance Program.

I certify that I do not have coverage for prescription drugs under Medicare, Medicaid, or any other public or private insurance plan, nor am I able to receive XIAFLEX under any other assistance program.

I understand that Auxilium Pharmaceuticals, the sponsor of the XIAFLEX Patient Assistance Program, reserves the right to modify or discontinue this program with respect to any patient, or in its entirety, at any time. I also understand that, although XIAFLEX may be given to me at no charge now, this does not mean I will be entitled to receive it at no charge indefinitely.

I consent to the release and disclosure of personal information, including my medical records, name, Social Security number, address, and date of birth to Auxilium Pharmaceuticals, its agents, distributors, or other designated representatives who may need my personal information to process this application, assure continuity of care, and in order for me to receive XIAFLEX at no charge. I hereby expressly authorize my physician to release to the XIAFLEX Patient Assistance Program all information that may be required in connection with this application. I also authorize the XIAFLEX Patient Assistance Program, Auxilium Pharmaceuticals, and their agents, to release medical information and related information to each other in order for me to receive XIAFLEX. I understand that this information will not be used for any other purpose unless I give written consent, the government requires it, or the XIAFLEX Patient Assistance Program removes my name and any other identifying information.

I hereby certify the accuracy of the information submitted on, and in connection with, this application. I also acknowledge that Auxilium Pharmaceuticals has the right to verify my eligibility for this Patient Assistance Program, to audit reported financial and insurance information and medical records, to contact me directly to confirm receipt of XIAFLEX, and to revise, change, or terminate this program at any time.

Patient Signature  Date

*Auxilium Pharmaceuticals reserves the right to make an independent determination of financial and medical need.*

Please send this completed form to: XIAFLEX Patient Assistance Program c/o Covance Health Market Access Services, PO Box 4280, Gaithersburg, MD 20885-4280  
Phone: 1-877-XIAFLEX (1-877-942-3539)

**Authorization & Consent For Treatment with injectable clostridial collagenase (Xiaflex) for Dupuytren's contracture**

I, \_\_\_\_\_, as a patient of the Indiana Hand to Shoulder Center, hereby request and authorize Dr. \_\_\_\_\_, his associates and assistants, to perform treatment of my Dupuytren's contracture with injectable clostridial collagenase (Xiaflex), including all necessary related procedures such as, but not limited to, dressings, local or regional anesthesia, splinting, and subsequent finger manipulation procedure.

I understand that up to three injections per joint may be necessary for maximal improvement, and that injections must be separated by approximately 4 weeks. Following injection, a finger manipulation will be required on a subsequent day. Response to collagenase varies from patient to patient, and from injection to injection.

I accept the risks associated with injectable clostridial collagenase including, but not limited to, failure to respond or incomplete response, possible need for additional injections, recurrence of disease and/or contracture, allergic / anaphylactic reaction, damage to tendons or ligaments (including tendon or pulley rupture), injection site pain, swelling, bruising, itching, lymph node swelling and/or pain, rash, nerve or vascular injury, skin tearing, infection, and other unknown complications.

I understand that my medical information may be disclosed to a friend or family member who is involved in my medical care. I consent to observers being present for educational purposes during this procedure, if such observers have been approved by my Physician.

I also consent to the photographing and/or videographing of my upper extremity in connection with the above procedure for medical, scientific, or educational purposes, provided my identity is not revealed by the pictures or by descriptive text accompanying them. All videos and photographs may be taken only with the consent of my Physician.

I further consent to be transferred to St. Vincent Hospital if conditions arise during or after the procedure, that in the judgment of my Physician or his assistants, deem it necessary for treatment in an emergency room.

**The undersigned certifies that he/she has read and fully understands the above Authorization for Treatment with injectable clostridial collagenase (Xiaflex)**, the reasons why the above treatment is considered, its advantages and possible complications, if any, as well as possible alternative modalities of treatment, which were explained by my physician.

I hereby certify that no guarantee or assurance has been made as to the results that may be obtained by this treatment.

I (We) certify that I am the patient; or the guardian, custodian, or nearest relative of the patient named above and have executed the authorization on their behalf.

Date of  
Service:

Joint Injected

Signature of Patient  
(or Patient's legal representative)

Date Signed

Time

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## DUPUYTREN'S PATIENTS DISCHARGE INSTRUCTIONS

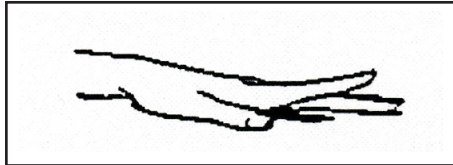
1. **LIMIT Use and Motion of your injected hand until you return for your manipulation. Keep the hand elevated until you go to sleep. DO NOT ice your hand or apply heat.**
2. You may remove the gauze dressing before you go to bed, if desired. If the dressing feels tight, you SHOULD remove it and then re-wrap it loosely. If the dressing is comfortable, you may leave it on until you return. Your finger/hand may be swollen, sore, and bruised. This is a normal reaction after injection. You may experience the feeling of being sore and tender in your forearm, elbow and armpit. This is also common after this injection. If you notice the tip of the injected hand/finger is extremely swollen and black and blue where it is visible and you want to come into the hospital to see your doctor, or you have any concerns and questions and want to discuss with your doctor, use the following number 317-875-9105.
3. During the afternoon or night after your injection, if you can't feel the tips of your fingers or if you have any adverse reaction that is of great concern to you, use the number above to get in touch with your doctor. Please do not call simply to report that your hand is tender and sore and black and blue. These are normal reactions after an injection.
4. You can move your fingers normally the day after the injection. The hand may be tender and sore. Avoid any use of the injected finger.
5. On your first follow-up appointment, you will be seen by your doctors for evaluation and finger manipulation and then fitted with a hand splint to be worn only at night when you are sleeping. The splint should be used for at least four weeks after the injection while you are sleeping, or until the inflammation has resolved.
6. Although it is safe to resume most normal activities after treatment with collagenase, it is important to **AVOID ALL ACTIVITIES THAT REQUIRE FORCEFUL GRIPPING FOR FOUR WEEKS.**



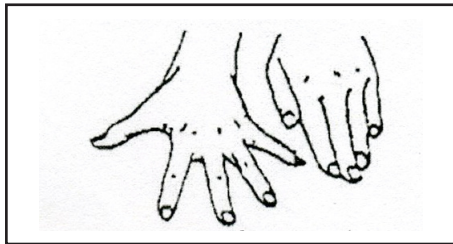
## Instructions for Subject's at Home Hand Therapy Exercises

After the initial follow-up visit (next day after injection), you need to wear a splint at night for up to 4 months. You are also required to perform an at-home finger extension and flexion exercises according to the following instructions.

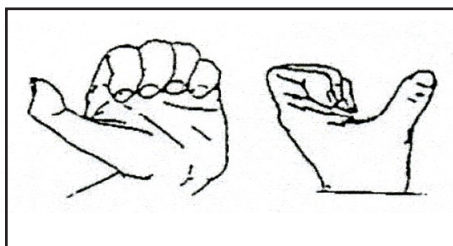
1. Lay hand flat on table. Raise each finger up one at a time; hold for 5 seconds; repeat 10 times. Repeat exercise 4 times a day.



2. Lay hand flat on table. Move each finger from side to side (like a windshield wiper) one at a time; repeat 10 times. Repeat exercise 4 times a day.



3. Bend only top 2 joints keeping large knuckles straight. Arch large knuckles back. Repeat exercise 4 times a day.



Arch back 10 times

4. Use unaffected hand to straighten finger that is affected 10 times holding for 5-10 seconds. Repeat exercise 4 times a day.

### In addition:

- Wear splint at night time.
- Resume your normal everyday activities, avoid forceful gripping for 4 weeks.
- Bring your splint with you on your next visit as it may need to be adjusted. If the splint becomes loose, or is not fitting well before your next appointment, please call the therapy department for a splint adjustment.