

XIAFLEX®

collagenase clostridium histolyticum



TRAINING GUIDE FOR THE ADMINISTRATION OF XIAFLEX® FOR DUPUYTREN'S CONTRACTURE

This Training Guide for the use of XIAFLEX for the treatment of adult patients with Dupuytren's contracture with a palpable cord is required and approved by the Food and Drug Administration (FDA) as part of the XIAFLEX Risk Evaluation and Mitigation Strategy (REMS). A REMS is a strategy to manage known or potential serious risks associated with a drug and is required by the FDA to ensure that the benefits of the drug outweigh its risks.

Auxilium has worked with the FDA to develop this Training Guide to inform healthcare providers about the risks of XIAFLEX, including tendon rupture and other serious adverse events of the injected extremity, and the potential risk of severe hypersensitivity events. This Training Guide also provides instructions on the proper preparation and administration of XIAFLEX for the treatment of Dupuytren's contracture to reduce the risks of serious adverse events of the injected extremity.

Please see Prescribing Information and Medication Guide.

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Please see Prescribing Information and Medication Guide.

Dupuytren's Contracture Overview

Dupuytren's contracture, a slowly progressive fibroproliferative disease of the palmar fascia in the hand, is characterized by increased collagen production and deposition that commonly results in cord formation. The Dupuytren's cord(s) may cause the affected fingers to bend or contract toward the palm of the hand, resulting in the inability to fully extend the affected fingers and a reduced range of motion.

XIAFLEX[®] (collagenase clostridium histolyticum) is indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord. XIAFLEX consists of 2 microbial collagenases that are isolated and purified from the fermentation of *Clostridium histolyticum*. The collagenases work in a synergistic fashion to provide hydrolyzing activity to collagen in the Dupuytren's cords. This guide demonstrates the steps necessary to prepare and administer XIAFLEX. It also outlines the finger extension procedure(s) that may be required approximately 24 to 72 hours after injection to help disrupt the cord. The guide also includes special precautions for injection of a cord affecting the PIP joint of the fifth finger.

XIAFLEX should be administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture.

XIAFLEX® Dosing for Dupuytren's Contracture

- XIAFLEX® (collagenase clostridium histolyticum), supplied as a lyophilized powder, **must be reconstituted with the supplied sterile diluent in the appropriate volume prior to use**
- The dose for XIAFLEX is 0.58 mg per injection into a palpable cord with a contracture of a metacarpophalangeal (MP) joint or a proximal interphalangeal (PIP) joint, according to the injection procedure
- Up to two concurrent injections may be administered in the same hand at one treatment visit to treat two joints affected by one or two cords
- XIAFLEX treatment of cords associated with contractures of distal interphalangeal (DIP) joints or the joints of the thumb has not been evaluated in clinical trials
- Finger extension procedure(s) may be performed approximately 24 to 72 hours after injection in the event the cord has not spontaneously ruptured
- Four weeks after the XIAFLEX injection and finger extension procedure(s), if an MP or PIP contracture remains, the cord may be re-injected with a single dose of 0.58 mg of XIAFLEX and the finger extension procedure(s) may be repeated (approximately 24 to 72 hours after re-injection)

Please see Prescribing Information and Medication Guide.

- Injection and finger extension procedure(s) may be administered up to **3 times per cord at approximately 4-week intervals**
- Perform up to two injections in the same hand according to the injection procedure appropriate for each joint type during a treatment visit for a total dose of up to 1.16 mg per visit. Two palpable cords affecting two joints may be injected or one palpable cord affecting two joints in the same finger may be injected at two locations during a treatment visit. When injecting a cord affecting the PIP joint of the fifth finger, special precautions should be taken (see WARNINGS AND PRECAUTIONS in the FDA-approved Prescribing Information)

XIAFLEX® Preparation for Administration for Dupuytren's Contracture

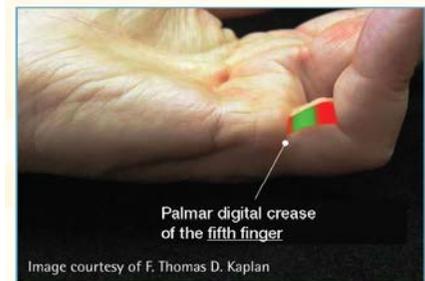
This section summarizes the procedure for reconstitution of the lyophilized XIAFLEX® (collagenase clostridium histolyticum) powder.

Important Considerations

- XIAFLEX should be injected into the cord at the point of maximal separation between the cord and the underlying tendon to prevent accidental injection into the tendon or surrounding tissue
- Care must be taken to place the needle in the cord and not through the cord
- Special care also should be taken when treating the PIP joint of the fifth finger (see below)

If injecting into a cord affecting the PIP joint of the fifth finger, the needle insertion should not be more than 2 to 3 mm in

depth and care should be taken to inject as close to the palmar digital crease as possible (as far proximal to the digital PIP joint crease). Tendon ruptures have occurred after XIAFLEX injections near the digital fifth finger PIP joint crease.



Please see Prescribing Information and Medication Guide.

Additional Important Considerations

- Prior to reconstitution, the vials of lyophilized XIAFLEX powder and sterile diluent should be stored in a refrigerator at 2° to 8°C (36° to 46°F)
- If the vials have been at room temperature for more than 60 minutes, they should not be used
- The preparation procedure varies slightly depending on whether the palpable cord is associated with an MP or PIP joint contracture and is described in detail below
- Visually inspect the vial containing XIAFLEX. The cake of lyophilized powder should be intact and white in color.

If the cake has been eroded, it should not be used and should be reported to Auxilium by calling 1-877-663-0412



XIAFLEX® Preparation for Administration for Dupuytren's Contracture (continued)

XIAFLEX is supplied in a single-use glass vial containing 0.9 mg of a sterile, lyophilized powder for reconstitution. The vial of lyophilized XIAFLEX powder should be reconstituted with the



sterile diluent (0.3 mg/mL calcium chloride dihydrate in 0.9% sodium chloride) provided in a single-use vial in the package. Syringes are not included in the package. Each vial of XIAFLEX and sterile diluent should only be used for a single injection. If a second joint requires treatment, separate vials and syringes should be used for the second injection.

Before Use

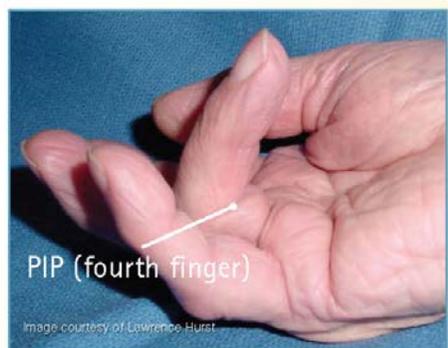
Before removing the vials from the refrigerator, confirm that the joint to be treated has a palpable cord. This is important particularly when performing a second or third XIAFLEX injection.

The vial containing the lyophilized XIAFLEX powder and the vial containing the sterile diluent for reconstitution should be removed from the refrigerator and allowed to stand at room temperature for at least 15 minutes, but no longer than 60 minutes prior to reconstitution.

Please see Prescribing Information and Medication Guide.

Using an aseptic technique, the following procedure for reconstitution should be followed:

1. Identify the joint contracture that is associated with the palpable cord (ie, MP or PIP) — the volume of sterile diluent required for reconstitution is determined by the type of joint contracture. When injecting XIAFLEX into a Dupuytren's cord affecting the PIP joint of the fifth finger, special precautions should be taken (see WARNINGS AND PRECAUTIONS in the FDA-approved Prescribing Information)



2. Remove the protective covering from both vials
3. Using sterile alcohol, swab the rubber stoppers and surrounding surface of the vial containing lyophilized XIAFLEX powder and the vial containing the sterile diluent for reconstitution

XIAFLEX® Preparation for Administration for Dupuytren's Contracture (continued)



4. Using a syringe that contains 0.01 mL graduations with a 27-gauge $\frac{1}{2}$ -inch needle (not supplied), withdraw the appropriate amount of **sterile diluent required for reconstitution** as follows:
 - **0.39 mL for a cord affecting an MP joint or**
 - **0.31 mL for a cord affecting a PIP joint**
5. When reconstituting XIAFLEX powder, inject the sterile diluent slowly into the sides of the vial containing the lyophilized XIAFLEX powder



Please see Prescribing Information and Medication Guide.

6. Slowly swirl the solution to ensure that all of the lyophilized powder has gone into the solution. Do not shake the solution because it can denature the proteins



7. The reconstituted XIAFLEX solution is now ready for injection (see “XIAFLEX Injection Procedure” for the appropriate injection volumes)

8. Discard the sterile diluent vial and the syringe and needle used for reconstitution

XIAFLEX® Preparation for Administration for Dupuytren's Contracture (continued)

Important Considerations

- The reconstituted XIAFLEX solution should be clear. Inspect the solution for particulate matter and discoloration prior to administration. If the solution contains particulates, is cloudy, or is discolored, do not inject it
- Reconstituted XIAFLEX solution can be kept at room temperature (20° to 25°C / 68° to 77°F) for up to 1 hour or refrigerated (2° to 8°C / 36° to 46°F) for up to 4 hours prior to administration. If refrigerated, the reconstituted XIAFLEX solution should be allowed to return to room temperature for approximately 15 minutes before use



Please see Prescribing Information and Medication Guide.

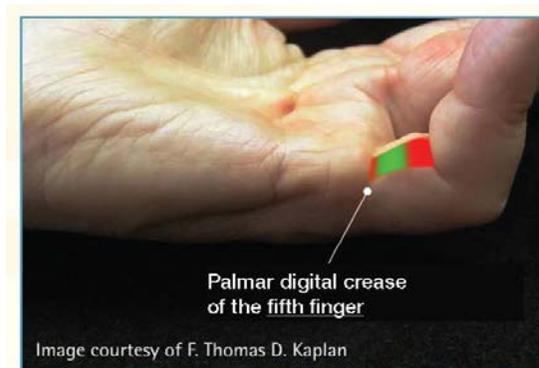
XIAFLEX® Injection Procedure for Dupuytren's Contracture

This section outlines the procedure for injecting the reconstituted XIAFLEX® (collagenase clostridium histolyticum) solution into the Dupuytren's cord.

Important Considerations

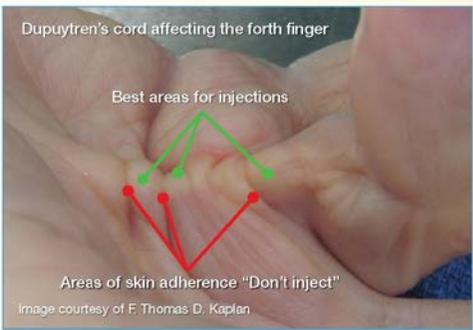
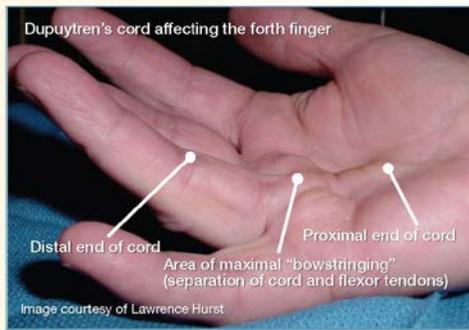
- XIAFLEX should be injected into the cord at the point of maximal separation between the cord and the underlying tendon to prevent accidental injection into the tendon or surrounding tissue
- Care must be taken to place the needle in the cord and not through the cord
- Special care also should be taken when treating the PIP of the fifth finger (see below)

If injecting into a cord affecting the PIP joint of the fifth finger, the needle insertion should not be more than 2 to 3 mm in depth and care should be taken to inject as close to the palmar digital crease as possible (as far proximal to the digital PIP joint crease). Tendon ruptures have occurred after XIAFLEX injections near the digital fifth finger PIP joint crease.



XIAFLEX[®] Injection Procedure for Dupuytren's Contracture (continued)

Administration of a local anesthetic agent prior to injection of XIAFLEX is not recommended because it may interfere with proper injection placement.



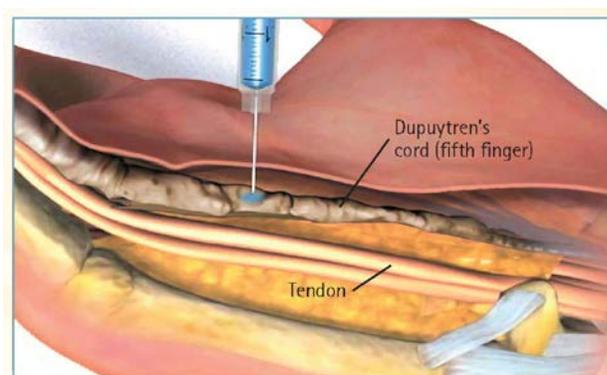
1. Reconfirm the cord and site chosen for injection. It should be the area where the contracting cord is separated maximally from the underlying flexor tendons and where the skin is not adhered intimately to the cord
2. Instruct patient to remove any jewelry from the hand to be treated
3. Prepare the skin with an antiseptic and allow it to dry

Please see Prescribing Information and Medication Guide.

4. Withdraw the volume of **reconstituted XIAFLEX solution*** required for injection using a hubless syringe with 0.01-mL graduations and a permanently fixed, 27-gauge ½-inch needle

- **Cord affecting an MP joint: Withdraw 0.25 mL of the reconstituted solution**
- **Cord affecting a PIP joint: Withdraw 0.20 mL of the reconstituted solution**

5. Secure the patient's hand to be treated while simultaneously applying tension to the cord. Place the needle into the cord, using caution to keep the needle within the cord, which has a gritty and gristly consistency. Avoid passing the needle tip completely through the cord to minimize the potential for injection of XIAFLEX into other tissues



* Each reconstituted volume withdrawn will contain the required dose of 0.58 mg of XIAFLEX. The entire reconstituted XIAFLEX solution contains 0.9 mg of XIAFLEX. Reconstituted XIAFLEX solution remaining in the vial after the injection should be discarded.

XIAFLEX[®] Injection Procedure for Dupuytren's Contracture (continued)

6. After needle placement, if there is any concern that the needle is in the flexor tendon, apply a small amount of passive motion at the distal interphalangeal (DIP) joint to ascertain that the needle does not move with fingertip motion. If insertion of the needle into a tendon is suspected or paresthesia is noted by the patient, withdraw the needle and reposition it into the Dupuytren's cord
7. After confirming that the needle is placed correctly in the cord, inject approximately one-third of the dose. It is important to stabilize the needle while pushing the plunger to prevent accidental injection through the cord
8. Withdraw the needle tip from the cord and reposition it in a slightly more distal location to the initial injection in the cord (approximately 2 to 3 mm) and inject another one-third of the dose

Please see Prescribing Information and Medication Guide.

9. Again, withdraw the needle tip from the cord and reposition it proximal to the initial injection (approximately 2 to 3 mm) and inject the final portion of the dose into the cord



An alternate method of injection may be used, in which the needle is completely withdrawn from the skin when being repositioned in the cord (approximately 2 to 3 mm to each side of the initial injection).

10. When injecting a cord affecting the PIP joint of the fifth finger, the needle insertion should not be more than 2 to 3 mm in depth and avoid injecting more than 4 mm distal to the palmar digital crease

XIAFLEX® Injection Procedure for Dupuytren's Contracture (continued)

11. Administer up to two injections in the same hand according to the injection procedure during a treatment visit.

When injecting two cords in the same hand concurrently, begin with the affected finger in the most lateral aspect of the hand and continue toward the medial aspect (eg, fifth finger to index finger).

Within each finger, begin with the affected joint in the most proximal aspect of the finger and continue toward the distal aspect (eg, MP to PIP).

Where a single cord affects both the MP and PIP joint in the same finger, administer one injection into the cord at the MP level and administer a second injection into the cord at the PIP level during the treatment visit. Each injection contains a 0.58 mg dose.

When administering two injections in the same hand during a treatment visit, use a new syringe and needle and separate vial of reconstituted solution for the second injection.

Please see Prescribing Information and Medication Guide.

12. After the injections are completed, wrap the patient's treated hand with a soft, bulky gauze dressing. Instruct the patient to return the next day and keep the treated hand elevated until bedtime



13. Patients should be informed that the injection may result in swelling, bruising, bleeding and/or pain at the injection site and surrounding tissue. Patients should be instructed to limit motion of the injected finger and promptly contact their physician if there is evidence of infection, sensory changes, or trouble bending the finger after swelling has gone down

Important Considerations

- Discard the unused portion of the reconstituted solution after injection
- Do not store, pool, or use any vials with unused, reconstituted solution

Finger Extension Procedure(s)

This section describes the finger extension procedure(s) that are usually performed approximately 24 to 72 hours after the XIAFLEX[®] (collagenase clostridium histolyticum) injection to rupture the Dupuytren's cord.

1. Determine if the contracture has resolved at the follow-up visit approximately 24 to 72 hours after XIAFLEX injection
2. If a contracture remains, a passive finger extension procedure should be undertaken in an attempt to disrupt the cord
3. Local anesthesia may be used during the finger extension procedure since the procedure can be painful for the patient

Please see Prescribing Information and Medication Guide

4. With the patient's wrist in a flexed position, apply moderate stretching pressure to the injected cord by extending the finger for approximately 10 to 20 seconds. For cords affecting the PIP joint, perform the finger extension procedure when the MP joint is in the flexed position. Do not jerk the finger to attempt to disrupt the cord, as this may contribute to tendon rupture. If two joints in one finger were treated, perform the finger extension procedure on the affected MP joint before performing the finger extension procedure on the affected PIP joint.

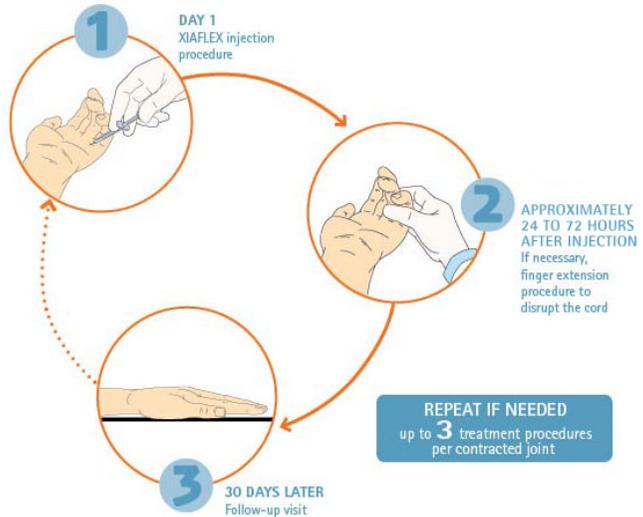


Finger Extension Procedure(s) (continued)

5. During this visit (approximately 24 to 72 hours after the XIAFLEX injection), if the first finger extension procedure does not result in rupture of the cord, a second and third attempt can be performed in 5- and 10-minute intervals. However, no more than 3 attempts to rupture a cord are recommended during this visit.

Please see Prescribing Information and Medication Guide

6. If the cord has not ruptured after 3 attempts of extension per joint, a follow-up visit should be scheduled in approximately 4 weeks. If the contracted cord persists at that subsequent visit, an additional XIAFLEX[®] injection and subsequent finger extension procedure may be repeated



In 2 XIAFLEX clinical trials, 64% and 44% of the XIAFLEX-treated patients, compared to 7% and 5% of the placebo-treated patients, achieved reduction in contracture of the primary joint (MP or PIP) to 0° to 5° after up to 3 injections.

Finger Extension Procedure(s) (continued)

7. Care should be taken during release of contracture, as some patients may experience skin splitting. If this occurs, cover the area with gauze and apply gentle pressure until bleeding stops. Standard wound care with regular dressings should be applied



8. Following the finger extension procedure(s), patients should be fitted with a splint and provided instructions for use at bedtime for up to 4 months to maintain finger extension. Instruct the patient to perform finger extension and flexion exercises several times a day for several months. Patients can be instructed to resume normal activities, but should not perform strenuous activity with the injected hand until instructed to do so

Please see Prescribing Information and Medication Guide

XIAFLEX[®] Indication and Important Safety Information for the treatment of Dupuytren's contracture

INDICATION

XIAFLEX[®] (collagenase clostridium histolyticum) is indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord.

IMPORTANT SAFETY INFORMATION

XIAFLEX is contraindicated in patients with a history of hypersensitivity to XIAFLEX or to collagenase used in any other therapeutic application or application method.

In the controlled and uncontrolled portions of clinical trials, flexor tendon ruptures occurred after XIAFLEX injection. Injection of XIAFLEX into collagen-containing structures such as tendons or ligaments of the hand may result in damage to those structures and possible permanent injury such as tendon rupture, ligament damage, or skin laceration. Therefore, XIAFLEX[®] should be injected only into the collagen cord with a MP or PIP joint contracture, and care should be taken to avoid injecting into tendons, nerves, blood vessels, or other collagen-containing structures of the hand. When injecting a cord affecting a PIP joint of the fifth finger, insert the needle no more than 2 to 3 mm in depth, and avoid injecting more than 4 mm distal to the palmar digital crease.

Other serious local adverse reactions in clinical trials include: pulley rupture, ligament injury, complex regional pain syndrome (CRPS), and sensory abnormality of the hand.

XIAFLEX® Indication and Important Safety Information for the treatment of Dupuytren's contracture (continued)

In a historically controlled post-marketing trial, the incidence of skin laceration (22%) was higher for subjects treated with two concurrent injections of XIAFLEX compared with subjects treated with up to three single injections in the placebo-controlled studies (9%). Cases of skin laceration requiring skin graft after finger extension procedures have been reported post-marketing.

In the controlled portions of the clinical trials (Studies 1 and 2), a greater proportion of XIAFLEX-treated patients (15%) compared to placebo-treated patients (1%) had mild allergic reactions (pruritus) after up to 3 injections. The incidence of XIAFLEX-associated pruritus increased after more XIAFLEX injections.

Because XIAFLEX contains foreign proteins, severe allergic reactions to XIAFLEX can occur. Anaphylaxis was reported in a post-marketing clinical trial (Study 3) in one patient who had previous exposure to XIAFLEX for the treatment of Dupuytren's contracture. Healthcare providers should be prepared to address severe allergic reactions following XIAFLEX injections.

Please see Prescribing Information and Medication Guide

In the XIAFLEX trials (Studies 1 and 2), 70% and 38% of XIAFLEX-treated patients developed an ecchymosis/contusion or an injection site hemorrhage, respectively. The efficacy and safety of XIAFLEX in patients receiving anticoagulant medications (other than low-dose aspirin) within 7 days prior to XIAFLEX administration is not known. Therefore, use with caution in patients with coagulation disorders including patients receiving concomitant anticoagulants (except for low-dose aspirin).

The most frequently reported adverse drug reactions ($\geq 5\%$) in the XIAFLEX clinical trials and at an incidence greater than placebo included: edema peripheral, contusion, injection site hemorrhage, injection site reaction, pain in extremity, tenderness, injection site swelling, pruritus, lymphadenopathy, skin laceration, lymph node pain, erythema, and axillary pain.

XIAFLEX® Indication and Important Safety Information for the treatment of Dupuytren's contracture (continued)

Read the FDA-approved Prescribing Information for XIAFLEX for an understanding of the benefits and risks of XIAFLEX in the treatment of adult patients with Dupuytren's contracture with a palpable cord.

Distribute the XIAFLEX Medication Guide to your patients and counsel each on the associated risks of treatment.

If you have product-related questions, please contact the Auxilium Drug Information Center at 1-877-663-0412.

To report adverse events, please contact either of the following:

- Auxilium Drug Information Center at 1-877-663-0412
- FDA MedWatch reporting system by telephone (1-800-FDA-1088), fax (1-800-FDA-0178), online (<https://www.accessdata.fda.gov/scripts/medwatch/>), or by mail using the postage-paid MedWatch Voluntary Reporting Form 3500.

Please mail to:

FDA Safety Information and Adverse Event
Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD, 20852-9787

Please see Prescribing Information and Medication Guide.

Frequently Asked Questions

1. What are the risks of XIAFLEX[®] (collagenase clostridium histolyticum) use in the treatment of Dupuytren's contracture?

In the XIAFLEX clinical studies, serious injury of the injected extremity including flexor tendon ruptures occurred after XIAFLEX injection.

Injection of XIAFLEX into collagen-containing structures, such as tendons or ligaments of the hand, may result in damage to those structures and possible permanent injury, such as tendon rupture or ligament damage.

Therefore, XIAFLEX should be injected only into the collagen cord causing an MP or PIP joint contracture, and care should be taken to avoid injecting into tendons, nerves, blood vessels, or other collagen-containing structures of the hand. Other events of the injected extremity included pulley rupture, ligament injury, recurrence of complex regional pain syndrome, tendonitis, and sensory abnormality of the hand.

Because XIAFLEX contains foreign proteins, severe allergic reactions, including anaphylaxis, can occur following XIAFLEX injections.

Healthcare providers should be prepared to address severe allergic reactions following XIAFLEX injections. Please see the Prescribing Information for additional information concerning XIAFLEX use.

Frequently Asked Questions (continued)

2. Why is a Risk Evaluation and Mitigation Strategy (REMS) program required for XIAFLEX for the treatment of Dupuytren's contracture?

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. The FDA has determined that a REMS is necessary to help mitigate the risks associated with XIAFLEX.

Auxilium has worked with the FDA to develop the XIAFLEX REMS program to inform healthcare providers and patients about the potential risks with XIAFLEX. The XIAFLEX REMS materials for healthcare providers, including this Training Guide and the Training Video, were designed to reduce the risk of tendon rupture and other serious adverse events.

3. What is the likelihood of tendon rupture?

Of the 1,082 patients who received 0.58 mg of XIAFLEX in the controlled and uncontrolled portions of the XIAFLEX studies (2,630 XIAFLEX injections), 3 (0.3%) patients had a flexor tendon rupture of the injected finger. The incidence of XIAFLEX-associated tendon ruptures in clinical practice may be different than the incidence seen in the XIAFLEX clinical studies.

Please see Prescribing Information and Medication Guide

4. Were there any allergic reactions to XIAFLEX®?

Anaphylaxis was reported in a post-marketing clinical trial in one patient who had previous exposure to XIAFLEX for the treatment of Dupuytren's contracture. Healthcare providers should be prepared to address severe hypersensitivity reactions (including anaphylaxis) following XIAFLEX injections.

In the controlled portions of the clinical trials (Studies 1 and 2), a greater proportion of XIAFLEX-treated patients (15%) compared with placebo-treated patients (1%) had mild hypersensitivity reactions (pruritus) after up to 3 injections. The incidence of XIAFLEX-associated pruritus increased after more XIAFLEX injections.

5. What is my responsibility when I prescribe/administer XIAFLEX for the treatment of Dupuytren's contracture?

You should read the Prescribing Information. The Prescribing Information and training materials include important information regarding the proper injection of XIAFLEX and the finger extension procedure(s) designed to mitigate the risks of tendon rupture, special precautions for injection of a cord

Frequently Asked Questions (continued)

affecting the PIP joint of the fifth finger, and other serious adverse events of the injected extremity. Secondly, a Medication Guide should be dispensed to each patient receiving XIAFLEX. This Medication Guide contains information that can be used to facilitate discussions about the potential risks of XIAFLEX. It is important to counsel patients about the risks associated with XIAFLEX including tendon rupture, other serious adverse events of the injected extremity, and the potential risk of serious hypersensitivity reactions (including the potential for anaphylaxis).

The Prescribing Information and the Medication Guide will be included in the product packaging and also can be found at www.XIAFLEX.com. For additional information, visit www.XIAFLEX.com or contact the toll-free medical information line (1-877-XIAFLEX; 1-877-942-3539).

To report adverse events, please contact either of the following: Auxilium Drug Information Center at 1-877-663-0412 or the FDA MedWatch reporting system by telephone (1-800-FDA-1088), fax (1-800-FDA-0178), or online (<https://www.accessdata.fda.gov/scripts/medwatch/>).

Please see Prescribing Information and Medication Guide.

Access to XIAFLEX® for the treatment of Dupuytren's contracture

XIAFLEX® is only available through a managed distribution program for the treatment of Dupuytren's contracture.

The enrollment process consists of 3 steps:

1. Review the training materials
2. Complete, sign, and fax or mail the healthcare provider enrollment form to be able to order XIAFLEX
3. Complete, sign, and fax or mail the site enrollment form to register site(s) for shipping

More details can be found at www.XIAFLEXREMS.com.

Please see Prescribing Information and Medication Guide