INDICATION

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

IMPORTANT SAFETY INFORMATION FOR XIAFLEX

- 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 in Dupuytren's contracture, 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 with a metacarpophalangeal (MP) or proximal interphalangeal (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, 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
- Other XIAFLEX-associated serious local adverse reactions in the controlled and uncontrolled portions of the clinical studies included pulley rupture, ligament injury, complex regional pain syndrome (CRPS), sensory abnormality of the hand, and skin laceration (tear). 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 premarketing trials (9%). Post-marketing cases of skin laceration requiring skin graft after finger extension procedures and local skin and soft-tissue necrosis, some requiring skin grafting, or other surgical interventions including finger amputation have been reported. Signs or symptoms that may reflect serious injury to the injected finger/hand should be promptly evaluated because surgical intervention may be required
- Cases of syncope and presyncope have been reported in the post-marketing period in patients treated with XIAFLEX. In most cases in patients with Dupuytren's contracture, the injection procedure, finger extension procedure, or pain following the procedures were reported as potential triggers for the events, suggesting a vasovagal mechanism. Most, but not all, cases occurred in the immediate treatment period (injection or finger extension procedure) or within 1 to 2 days following the injection or finger extension procedure. If presyncopal symptoms occur, patients should remain recumbent until symptoms resolve. Syncope may be associated with bodily injuries, including concussion, head abrasion, and other accidental injuries
- In the controlled portions of the clinical trials in Dupuytren's contracture, 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 in patients with Dupuytren's contracture
- Because XIAFLEX contains foreign proteins, severe allergic reactions to XIAFLEX can occur. 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 allergic reactions following XIAFLEX injections
- In the XIAFLEX trials in Dupuytren's contracture, 70% and 38% of XIAFLEX-treated patients developed an ecchymosis/contusion or an injection site hemorrhage, respectively. Patients with abnormal coagulation (except for patients taking low-dose aspirin, eg, up to 150 mg per day) were excluded from participating in these studies. Therefore, the efficacy and safety of XIAFLEX in patients receiving anticoagulant medications (other than low-dose aspirin, eg, up to 150 mg per day) within 7 days prior to XIAFLEX administration is not known. In addition, it is recommended to avoid use of XIAFLEX in patients with coagulation disorders, including patients receiving concomitant anticoagulants (except for low-dose aspirin)
- In the XIAFLEX clinical trials for Dupuytren's contracture, the most common adverse reactions reported in ≥25% of patients treated with XIAFLEX and at an incidence greater than placebo were edema peripheral (eg, swelling of the injected hand), contusion, injection site hemorrhage, injection site reaction, and pain in the injected extremity
- Post-marketing experience – Syncope and presyncope have been reported in patients treated with XIAFLEX. Most, but not all, cases occurred in the immediate treatment period or within 1 to 2 days following injection. Bodily injuries associated with the syncopal events have been reported

Click for full Prescribing Information and Medication Guide.

XIAFLEX®
collagenase clostridium histolyticum

XD-06686/August 2022

XIAFLEX®

☐ NEW Enrollment
☐ Enrollment Update

(collagenase clostridium histolyticum)

Managed Distribution Program for Dupuytren's Contracture

Program Use Only:
Healthcare Setting Enrollment ID #

Pharmacy/Healthcare Setting Enrollment Form for Dupuytren's Contracture

To enroll, the pharmacy or healthcare setting must designate an Authorized Representative to coordinate the setting's activities and assure compliance with the XIAFLEX® Managed Distribution Program for adults with Dupuytren's contracture with a palpable cord.

INSTRUCTIONS: Fax completed form to **XIAFLEX® at 877-313-1236** or mail to XIAFLEX® Managed Distribution Program, PO Box 2957, Phoenix, AZ 85062-2957. You will receive an enrollment confirmation within 2 business days after your form is received by Endo Pharmaceuticals Inc. For questions regarding the XIAFLEX® Managed Distribution Program for Dupuytren's contracture, call 877-313-1235.

AUTHORIZED REPRESENTATIVE RESPONSIBILITIES

I understand that XIAFLEX® is only available through the XIAFLEX® Managed Distribution Program for Dupuytren's contracture. I am the Authorized Representative designated by my pharmacy or healthcare setting to coordinate the activities of the XIAFLEX® Managed Distribution Program. I agree to comply with the following program requirements:

- Ensure that the staff responsible for dispensing and administering XIAFLEX® at this healthcare setting is aware of my responsibilities as the Authorized Representative.
- Prior to dispensing XIAFLEX®, confirm that the Healthcare Provider is enrolled in the XIAFLEX® Managed Distribution Program for Dupuytren's contracture.
- Maintain a current list of Healthcare Providers affiliated with my healthcare setting who are enrolled. The current affiliated Healthcare Providers of this healthcare setting include the individuals listed below. I will maintain this list by adding or removing affiliated Healthcare Providers as appropriate.
- Agree not to loan, sell, or transfer XIAFLEX® to another pharmacy, healthcare setting, prescriber, institution, or distributor.
- Make available to Endo Pharmaceuticals Inc., and/or a designated third party or the FDA, documentation to verify adherence to the requirements of the XIAFLEX® Managed Distribution Program.

I understand that this enrollment only applies to me as the designated Authorized Representative of this pharmacy or healthcare setting. I understand that my program status will be shared with Endo Pharmaceuticals Inc. I will complete a separate enrollment form for each pharmacy or healthcare setting (unique ship-to site address) for which my designation and responsibilities extend. Failure to enroll a pharmacy or healthcare setting in the XIAFLEX® Managed Distribution Program for Dupuytren's contracture will result in the inability to receive shipments of XIAFLEX®.

HCP First and Last Name | Healthcare Provider Enrollment ID #

For additional Affiliated Healthcare Setting Providers, please continue on page 2.

Authorized Representative (Please Print)

Signature | Date

SETTING INFORMATION

Healthcare Setting Name

Ship-to Address

Address 1

Address 2

City | State | ZIP

Setting Phone | Setting Fax

Provide at least one healthcare setting identifier:

DEA # | NPI #

HIN # | NCPDP #

Pharmacy or Healthcare Setting Type (Check one)

☐ Independent Practice
☐ Group Practice
☐ Institution Central Purchasing (owned or under the control of hospital system)
☐ Institution Direct Purchasing (owned or under the control of hospital system)
☐ Pharmacy (XIAFLEX® is not available for distribution by retail pharmacies. Retail pharmacies should not enroll.)

AUTHORIZED REPRESENTATIVE

Salutation: ☐ Dr ☐ Mr ☐ Ms ☐ Mrs

First Name | MI | Last | Suffix

Fax | Phone | Phone Type ☐ Main ☐ Direct ☐ Mobile

Email | Preferred method of contact is: ☐ Email ☐ Phone ☐ Fax ☐ Mail

Role: ☐ Office Staff ☐ Clinician/Healthcare Provider ☐ Office Administration ☐ Other (Specify)

Please see Important Safety Information on the first page.

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(collagenase clostridium histolyticum)

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AFFILIATED HEALTHCARE SETTING HEALTHCARE PROVIDERS

HCP First and Last Name	Healthcare Provider Enrollment ID #

XTRA
XIAFLEX® TRAINING
Resources for Administration

Please see Important Safety Information on the first page.

Click for full Prescribing Information and Medication Guide.

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