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 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, 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 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%). Cases of skin laceration requiring skin graft after finger extension procedures have been reported post-marketing. Signs or symptoms that may reflect serious injury to the injected finger/hand should be promptly evaluated because surgical intervention may be required
- 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 study 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

Please click here for full Prescribing Information, including Medication Guide.

XIAFLEX®
collagenase clostridium histolyticum

XD-05729/March 2019

XIAFLEX®
(collagenase clostridium histolyticum)

☐ NEW Enrollment
☐ Enrollment Update

Program Use Only:
Healthcare Provider Enrollment ID #

Managed Distribution Program for Dupuytren's Contracture

Healthcare Provider Enrollment Form for Dupuytren's Contracture

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.

Healthcare provider responsibilities for the use of XIAFLEX® in the treatment of adults with Dupuytren's contracture with a palpable cord:

I understand that XIAFLEX® is only available for the treatment of Dupuytren's contracture through the XIAFLEX® Managed Distribution Program. I confirm that I have met all of the following requirements:

- I am a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture.
- I have read and understand the full Prescribing Information for XIAFLEX®, including the risks associated with the use of XIAFLEX® and how to properly administer XIAFLEX® for Dupuytren's contracture.
- I have completed the XIAFLEX® procedure training video and/or training guide for Dupuytren's contracture.
- Prior to initiating treatment, and as part of each treatment-related visit, I agree to provide each patient with a Medication Guide and counsel each patient about the benefits and risks of XIAFLEX® prior to administering XIAFLEX®.
- I agree that I will make available to Endo Pharmaceuticals Inc., and/or a designated third party or the FDA documentation to verify understanding of, and adherence to, the XIAFLEX® managed distribution requirements for Dupuytren's contracture.

I understand that this enrollment only applies to me, and does not apply to any Healthcare Setting that employs me, or in which I may have an interest. I understand that my program status will be shared with Endo Pharmaceuticals Inc. Failure to enroll in the XIAFLEX® Managed Distribution Program for Dupuytren's contracture as a Healthcare Provider will result in my inability to receive shipments of XIAFLEX®.

Healthcare Provider Name | Signature | Date

HEALTHCARE PROVIDER INFORMATION

First Name | MI | Last | Suffix | Degree

☐ MD ☐ DO ☐ PA ☐ CNP

Fax | Phone | Phone Type

☐ Office ☐ Mobile ☐ Home

Email | Preferred method of contact is:

☐ Email ☐ Phone ☐ Fax ☐ Mail

NPI # | License # and State

Specialty: ☐ General Surgeon ☐ Plastic Surgeon ☐ Hand Surgeon ☐ Orthopedic Surgeon ☐ Rheumatologist ☐ Other (specify)

PRACTICE INFORMATION

Practice Name

Address 1 | Address 2

City | State | ZIP

Primary Treatment Setting: ☐ Inpatient ☐ Outpatient/Clinic (affiliated with hospital) ☐ Outpatient/Clinic (not affiliated with hospital)

XTRA
XIAFLEX® TRAINING
Resources for Administration

Please see Important Safety Information on the first page.

Please click here for full Prescribing Information, including Medication Guide.

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