

Xiaflex® (collagenase clostridium histolyticum)



When requesting Xiaflex® (collagenase clostridium histolyticum), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indications¹

- Xiaflex® (collagenase clostridium histolyticum) is indicated for the treatment of individuals with Dupuytren's contracture with a palpable cord.
- Xiaflex® (collagenase clostridium histolyticum) is indicated for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.

Approved Off-label Compensial uses²

- None

Coverage Guidelines

For all approved indications, the individual does **not** have the following contraindication or exclusion to therapy:

- Peyronie's plaques that involve the penile urethra¹
- Hypersensitivity to Xiaflex® (collagenase clostridium histolyticum) or to collagenase used in any other therapeutic application or application method¹

Dupuytren's Contracture

The individual must meet **all** of the following criteria for approval¹:

- Has a palpable cord
- Has a contracture of a metacarpophalangeal joint or a proximal interphalangeal joint
- No more than 3 injections per cord with 4 week intervals between injections

Approval duration: 16 weeks

Peyronie's Disease

The individual must meet **all** of the following criteria for approval¹:

- Has a palpable penile plaque
- Has objective documentation of a penile curvature deformity of at least 30 degrees at start of therapy
- Treatment will be administered in conjunction with a penile modeling procedure

- Up to four treatment cycles may be administered for each plaque causing the curvature deformity. Treatment cycles may be repeated at approximately six-week intervals

Approval duration: 36 weeks

Additional Information for Prescribers¹

Because of the risks of corporal rupture (penile fracture) or other serious penile injury in the treatment of Peyronie's disease, Xiaflex[®] (collagenase clostridium histolyticum) is available only through the Xiaflex REMS Program.

Required components of the Xiaflex[®] (collagenase clostridium histolyticum) REMS Program include the following:

- Prescribers must be certified with the program by enrolling and completing training in the administration of Xiaflex[®] (collagenase clostridium histolyticum) treatment for Peyronie's disease.
- Healthcare sites must be certified with the program and ensure that Xiaflex[®] (collagenase clostridium histolyticum) is only dispensed for use by certified prescribers.

Further information is available at www.XIAFLEXREMS.com or 1-877-313-1235.

Our prescribers are alerted to the following safety concerns as educational points/reminders:

- Avoid injecting Xiaflex[®] (collagenase clostridium histolyticum) into tendons, nerves, blood vessels, or other collagen-containing structure of the hand. Injection into these structures may result in possible permanent injury, such as tendon rupture, ligament damage, or skin laceration.
- Avoid injecting into the urethra, nerves, blood vessels, corpora cavernosa or other collagen-containing structures of the penis. Injection into these structures may result in possible permanent injury such as corporal rupture (penile fracture).
- If the curvature deformity is less than 15 degrees after the first, second or third treatment cycle, subsequent treatment cycles should not be administered.
- Healthcare providers should be prepared to address hypersensitivity reactions, including anaphylaxis, following Xiaflex[®] (collagenase clostridium histolyticum) injections.
- Use with caution, including inpatients who have received anticoagulant medications other than low-dose aspirin within 7 days of the injection.

Xiaflex[®] (collagenase clostridium histolyticum)

References

1. Xiaflex® prescribing information. Malvern, PA: Endo Pharmaceuticals Inc: August 2016.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 27, 2017. <https://www.micromedexsolutions.com>
3. ClinicalTrials.gov. A phase 2a, open-label, dose-ranging study of the safety and effectiveness of AA4500 for the treatment of adhesive capsulitis of the shoulder (03-17-2015). Accessed February 27, 2017. <https://www.clinicaltrials.gov/ct2/show/NCT01483963?term=NCT01483963&rank=1>.
4. ClinicalTrials.gov. A randomized, double-blind, placebo-controlled study of the safety and efficacy of AA4500 for the treatment of adhesive capsulitis of the shoulder (03-17-2015). Accessed February 27, 2017. <https://www.clinicaltrials.gov/ct2/show/NCT02006719?term=NCT02006719&rank=1>