

IMPORTANT SAFETY INFORMATION

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

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.

Although there were no severe allergic reactions observed in the XIAFLEX studies (e.g., those associated with respiratory compromise, hypotension, or end-organ dysfunction), severe reactions including anaphylaxis could occur following XIAFLEX injections. Healthcare providers should be prepared to address severe allergic reactions following XIAFLEX injections.

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.

Please see Full **Prescribing Information** and **MEDICATION GUIDE**.