

Medication Guide
XIAFLEX® (Zī a flex)
(collagenase clostridium histolyticum)
For injection, for intralesional use

XIAFLEX is approved for two uses: Dupuytren's contracture and Peyronie's disease. Information is provided separately for each use. Use for treating Dupuytren's contracture is described first, followed by use for treating Peyronie's disease.

Read this Medication Guide before you receive XIAFLEX for the treatment of Dupuytren's contracture and each time you get an injection. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is the most important information I should know about XIAFLEX for the treatment of Dupuytren's contracture?

XIAFLEX can cause serious side effects, including:

- 1. Tendon rupture or ligament damage.** Receiving an injection of XIAFLEX may cause damage to a tendon or ligament in your hand and cause it to break or weaken. This could require surgery to fix the damaged tendon or ligament. Call your healthcare provider right away if you have trouble bending your injected finger (towards the wrist) after the swelling goes down or you have problems using your treated hand after your follow-up visit.
- 2. Nerve injury or other serious injury of the hand. Call your healthcare provider right away** if you get numbness, tingling, increased pain, or tears in the skin (laceration) in your treated finger or hand after your injection or after your follow-up visit.
- 3. Hypersensitivity reactions, including anaphylaxis.** Severe allergic reactions can happen in people who receive XIAFLEX, because it contains foreign proteins.

Call your healthcare provider right away if you have any of these symptoms of an allergic reaction after an injection of XIAFLEX:

- hives
- swollen face
- breathing trouble
- chest pain
- low blood pressure
- dizziness or fainting

What is XIAFLEX?

XIAFLEX is a prescription medicine used to treat adults with Dupuytren's contracture when a "cord" can be felt. It is not known if XIAFLEX is safe and effective in children under the age of 18.

Who should not receive XIAFLEX?

Do not receive XIAFLEX if you:

- are allergic to collagenase clostridium histolyticum, or any of the ingredients in XIAFLEX, or to any other collagenase product. See the end of this Medication Guide for a complete list of ingredients in XIAFLEX.

Talk to your healthcare provider before receiving this medicine if you have any of these conditions.

What should I tell my healthcare provider before receiving XIAFLEX?

Before receiving XIAFLEX, tell your healthcare provider if you:

- have had an allergic reaction to a XIAFLEX injection in the past
- have a bleeding problem
- have received XIAFLEX to treat another condition
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if XIAFLEX will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if XIAFLEX passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive XIAFLEX.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Using XIAFLEX with certain other medicines can cause serious side effects.

Especially tell your healthcare provider if you take:

- medicines to thin your blood (anticoagulants). If you are told to stop taking a blood thinner before your XIAFLEX injection, your healthcare provider should tell you when to restart the blood thinner.

Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure.

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How will I receive XIAFLEX?

- XIAFLEX should be injected into a cord by a healthcare provider who is experienced in injection procedures of the hand and treating people with Dupuytren's contracture. If you have more than 1 contracture, your healthcare provider may give you 2 injections in 1 of your hands during your visit.
- Your healthcare provider will inject XIAFLEX into the cord that is causing your finger to bend.
- After an injection of XIAFLEX, your affected hand will be wrapped with a bandage. You should limit moving and using the treated finger after the injection.
 - **Do not** bend or straighten the fingers of the injected hand until your healthcare provider says it is okay. This will help to keep the medicine from leaking out of the cord.
 - **Do not** try to straighten the treated finger yourself.
- Keep the injected hand elevated until bedtime.
- **Call your healthcare provider right away if you have:**
 - signs of infection after your injection, such as fever, chills, increased redness, or swelling
 - numbness or tingling in the treated finger
 - trouble bending the injected finger after the swelling goes down
- Return to your healthcare provider's office as directed 1 to 3 days after your injection. During this first follow-up visit, if you still have the cord, your healthcare provider may try to extend the treated finger to "break" the cord and try to straighten your finger.
- Your healthcare provider will provide you with a splint to wear on the treated finger. Wear the splint as instructed by your healthcare provider at bedtime to keep your finger straight.
- Do finger exercises each day, as instructed by your healthcare provider.
- Follow your healthcare provider's instructions about when you can start doing your normal activities with the injected hand.

What are the possible side effects of XIAFLEX?

XIAFLEX may cause serious side effects, including:

- **See “What is the most important information I should know about XIAFLEX?”**
- **increased chance of bleeding.** Bleeding or bruising at the injection site can happen in people who receive XIAFLEX. Talk to your healthcare provider if you have a problem with your blood clotting. XIAFLEX may not be right for you.

The most common side effects with XIAFLEX for the treatment of Dupuytren’s contracture include:

- swelling of the injection site or the hand
- bruising or bleeding at the injection site
- pain or tenderness of the injection site or the hand
- swelling of the lymph nodes (glands) in the elbow or armpit (axilla)
- itching
- breaks in the skin
- redness or warmth of the skin
- pain in the armpit

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all of the possible side effects with XIAFLEX. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of XIAFLEX.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about XIAFLEX. If you would like more information, talk to your healthcare provider. You can ask your healthcare provider or pharmacist for information about XIAFLEX that is written for health professionals.

For more information, go to www.XIAFLEX.com or call 1-877-663-0412.

What are the ingredients in XI AFLEX?

Active ingredient: collagenase clostridium histolyticum

Inactive ingredients: hydrochloric acid, sucrose, and tromethamine. The diluent contains: calcium chloride dihydrate in 0.9% sodium chloride

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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