

MEDICATION GUIDE
XIAFLEX® (Zī a flex)
(collagenase clostridium histolyticum)

Read this Medication Guide before you receive XIAFLEX 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?

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, or increased pain in your treated finger or hand after your injection or after your follow-up visit.
3. **Allergic Reactions.** Allergic reactions can happen in people who take 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

What is XIAFLEX?

XIAFLEX is a prescription medicine used to treat adults with Dupuytren's contracture when a "cord" can be felt.

In people with Dupuytren's contracture, there is thickening of the skin and tissue in the palm of your hand that is not normal. Over time, this thickened tissue can form a cord in your palm. This causes one or more of your fingers to bend toward the palm, so you can not straighten them.

XIAFLEX should be injected into a cord by a healthcare provider who is skilled in injection procedures of the hand and treating people with Dupuytren's contracture. The proteins in XIAFLEX help to "break" the cord of tissue that is causing the finger to be bent.

It is not known if XIAFLEX is safe and effective in children under the age of 18.

What should I tell my healthcare provider before starting treatment with XIAFLEX?

XIAFLEX may not be right for you. Before receiving XIAFLEX, tell your healthcare provider if you:

- have had an allergic reaction to a previous XIAFLEX injection.
- have a bleeding problem.
- 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. It is not known if XIAFLEX passes into your breast-milk. Talk to 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 non-prescription medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you use:

- a blood thinner medicine such as aspirin, clopidogrel (PLAVIX[®]), prasugrel hydrochloride (EFFIENT[®]), or warfarin sodium (COUMADIN[®]). 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.

How will I receive XIAFLEX?

- 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 prevent 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 on the day 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 can cause serious side effects. See “What is the most important information I should know about XIAFLEX?”.

Common side effects with XIAFLEX include:

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

These are not all of the possible side effects with XIAFLEX. Tell your healthcare provider about any side effect that bothers you or does not go away.

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

General information about 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 for information about XIAFLEX that is written for health professionals. For more information visit www.XIAFLEX.com or call 1-877-663-0412.

What are the ingredients in XIAFLEX?

Active ingredient: collagenase clostridium histolyticum.

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

Manufactured and distributed by:
Auxilium Pharmaceuticals, Inc.
Malvern, PA 19355
USA

This label may not be the latest approved by FDA.
For current labeling information, please visit <https://www.fda.gov/drugsatfda>

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

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