

Replace eXactly what's missing



Coagadex[®]

Coagulation Factor X (Human)

The first and only treatment
specifically for hereditary
factor X deficiency

Patient Information

Please see Important Safety
Information on page 16 and full
prescribing information in pocket.

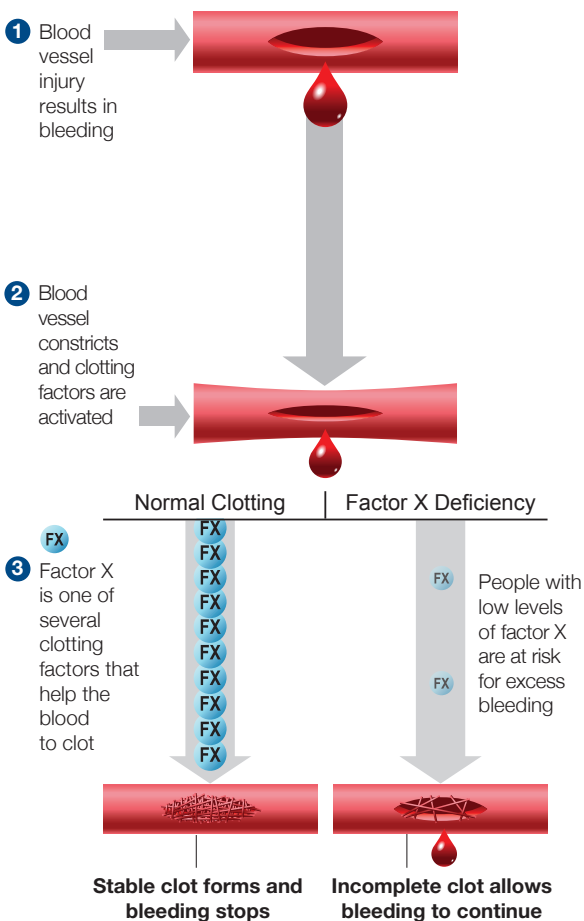
bpl
Bio Products Laboratory
a commitment for life

What is hereditary factor X deficiency?

Factor X deficiency is a rare bleeding disorder. It is caused by having too little of a protein called factor X in the blood.

- Factor X plays an important role in blood clotting (coagulation)
- People with factor X deficiency have a higher risk of excess bleeding

A Closer Look at Factor X Deficiency



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What causes hereditary factor X deficiency?

Factor X deficiency may be caused by a defect in the factor X gene that is passed down from parents to their children.

- To have hereditary factor X deficiency, a person must receive a defective factor X gene from both parents
- Hereditary factor X deficiency affects approximately 1 in every 1,000,000 people
- Hereditary factor X deficiency affects males and females at an equal rate

What are the symptoms of factor X deficiency?

The symptoms of factor X deficiency can range from mild to severe.

Symptoms of mild factor X deficiency may include:

- Easy bruising
- Nosebleeds
- Mouth bleeds
- Bleeding longer than normal after injury or surgery



Symptoms of severe factor X deficiency may include:

- Bleeding of umbilical cord
- Joint bleeds and bruising
- Intramuscular bleeds
- Spontaneous bleeding in the head, spinal cord, or gastrointestinal tract (for example: stomach or intestines)

Women with factor X deficiency may experience:

- Heavy or prolonged bleeding during menstruation (periods)
- Complications during pregnancy or childbirth

How is factor X deficiency diagnosed?

A healthcare provider may suspect a bleeding disorder like factor X deficiency based on:

- A personal history of bleeding symptoms
- A family history of a bleeding disorder

When factor X deficiency is suspected, the diagnosis is made through blood tests that measure the time it takes for blood to clot. These include:

- Prothrombin time (PT)
- Activated partial thromboplastin time (aPTT)

A blood test called a factor X assay will be used to confirm the diagnosis. This test measures the activity of factor X in the blood.

How is hereditary factor X deficiency treated?

Factor X deficiency is treated by replacing the factor X that is missing from the body. For many years, the only treatments available for factor X deficiency were products developed for other conditions.

- These other products contain multiple blood clotting factors, not just factor X. If blood levels of these other factors get too high, complications can occur
- These other products don't list exactly how much factor X is in each vial. As a result, these products can be difficult to dose accurately for hereditary factor X deficiency

The treatment of hereditary factor X deficiency changed with the approval of COAGADEX.

COAGADEX is the first product approved specifically to treat hereditary factor X deficiency

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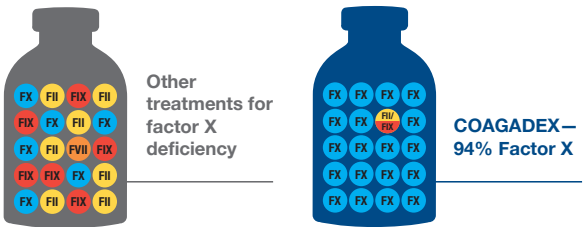
What is COAGADEX?

COAGADEX is a high-purity product that contains more than 94% factor X.

It is the first and only treatment specifically for people with factor X deficiency.

Until recently, the treatments available were designed for other diseases and contain larger amounts of other proteins, such as factors II and IX, in addition to factor X.

Taking these extra proteins when you don't need them can cause blood clots that may block blood vessels and cause serious injury (for example: stroke or blood clots in the lung or leg).



With COAGADEX, you get the factor X you need without a lot of other proteins that you don't need.

How does COAGADEX work?

COAGADEX replaces the factor X that is missing from the body. In a medical study, **98%** of bleeds were successfully treated with COAGADEX.¹



In another medical study where COAGADEX was used to reduce or prevent bleeds, doctors rated the efficacy of COAGADEX as “excellent”^{*} in all people in the study.²



^{*}Excellent=No minor or major bleeds occurred during the study period; or lower frequency of bleeds than expected given subject’s medical/treatment history.

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Ask your doctor if COAGADEX is right for you

If you want to talk to your healthcare provider about COAGADEX, the questions below may help.

Share your answers to the following questions with your healthcare provider and explain you would like to talk about whether COAGADEX is right for you.

1. How often do you have a bleed?
2. How satisfied are you with your current activity level?
 - Very satisfied
 - Somewhat satisfied
 - Not sure
 - Somewhat unsatisfied
 - Very unsatisfied
3. What are your treatment goals?
4. Do you think you need to make a change in how you are treating your hereditary factor X deficiency?
 - Yes
 - No
5. What questions or concerns do you have about your current treatment?
6. How satisfied are you with your current treatment in helping you meet your goals?
 - Very satisfied
 - Somewhat satisfied
 - Not sure
 - Somewhat unsatisfied
 - Very unsatisfied
7. How interested are you in trying COAGADEX?
 - Very interested
 - Somewhat interested
 - A little interested
 - Not interested
 - Not sure

What should I tell my healthcare provider before I use COAGADEX?

You should tell your healthcare provider if you:

- Have or previously had any medical problems
- Have any allergies
- Take any prescription and non-prescription medicines, including over-the-counter medicines, supplements or herbal medicines
- Are breast-feeding. It is not known if COAGADEX passes into your milk and if it can harm your baby
- Are pregnant or planning to become pregnant. It is not known if COAGADEX may harm your unborn baby
- Have been told you have inhibitors to factor X

What are the possible side effects of COAGADEX?

You can have an allergic reaction to COAGADEX.

Stop treatment and call your healthcare provider right away if you have any of the following symptoms: difficulty breathing, chest tightness, swelling of the face, rash or hives.

Common side effects of COAGADEX are infusion site redness, infusion site pain, tiredness, and back pain.

Your body can also make antibodies, called “inhibitors,” against COAGADEX, which may stop COAGADEX from working properly. Your healthcare provider may give you blood tests to check for inhibitors.

These are not all the possible side effects of COAGADEX. Tell your healthcare provider about any side effects that bother you or do not go away.

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COAGADEX is made from human plasma and may contain infectious agents, e.g. viruses, the variant Creutzfeldt-Jakob disease agent, and, theoretically, the Creutzfeldt-Jakob disease agent. No cases of transmission of viral diseases, vCJD or CJD, have been associated with the use of COAGADEX.



How is COAGADEX dosed?

COAGADEX is given by intravenous (IV) infusion. It may be infused in a healthcare provider’s office or infusion center, or you may be able to infuse the product in your home.

Your healthcare provider will tell you how much COAGADEX to use and how often to use it based on your age, your weight, the severity of your factor X deficiency, your bleeding history and (if you are currently experiencing a bleed) where you are bleeding.

COAGADEX is available in 250 IU or 500 IU range single-use vials that include a Mix2Vial™ for reconstitution.



Mix2Vial is a trademark of West Pharmaceutical Services.

How is COAGADEX prepared for use?

Do not attempt to administer your own infusion unless you have been taught how by your healthcare provider or hemophilia center.

COAGADEX must be reconstituted before use. Do not freeze or use any solution that has been frozen. COAGADEX must not be used if it is cloudy or contains any particles after reconstitution.

The procedures below and on the next 2 pages are provided as general guidelines for the preparation and reconstitution of COAGADEX. Always work on a clean surface and wash your hands before performing the following procedures:

- 1.** COAGADEX should be dissolved using the transfer device called Mix2Vial. The Mix2Vial transfer device is provided with the product for needle-free, easy and safe use
- 2.** COAGADEX must only be dissolved in the sterile water for injection provided with the product
- 3.** To administer this medicine you will also need a syringe and suitable needle (not provided in the COAGADEX carton)
- 4.** Bring the containers of COAGADEX and the sterile water for injection to room temperature before mixing
- 5.** The reconstitution process is detailed on the next 2 pages

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How do I store COAGADEX?

- Keep COAGADEX in its original package to protect it from light
- Store COAGADEX at room temperature [not to exceed 30°C (86°F)] or refrigerated [not below 2°C (36°F)].
Do not freeze
- Do not use after the expiration date printed on the box. The expiration date refers to the last day of that month
- Do not use the sterile water if any small particles can be seen in it
- After reconstitution (mixing with the sterile water), COAGADEX must be used within one hour. Discard any COAGADEX left in the vial at the end of your infusion



Instructions for reconstituting COAGADEX



Step 1

- Bring the vials of COAGADEX and sterile water to room temperature before mixing
- Remove the cap from the vial of COAGADEX and clean the top of the stopper with an alcohol swab
- Repeat this step with the vial of sterile water

Step 2

- Peel back the top of the Mix2Vial package but leave the device in the package.



Step 3

- Place the blue end of the Mix2Vial on the sterile water vial and push straight down until the spike penetrates the rubber stopper and snaps into place
- Remove the plastic outer packaging from the Mix2Vial and discard it. Do not touch the exposed end of the device



Step 4

- Turn the sterile water vial upside down with the device still attached
- Place the clear end of the Mix2Vial on the product vial and push straight down until the spike penetrates the rubber stopper and snaps into place

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**Step 5**

- The sterile water will be pulled into the vial of COAGADEX by the vacuum contained within it
- Gently swirl the vial to make sure the powder is thoroughly mixed. Do not shake the vial
- A clear or slightly pearl-like solution should be obtained, usually in less than 1 minute (5 minutes maximum)

Note: If the water is not pulled into the vial of COAGADEX, this indicates a loss of vacuum in the vial. Do not use the product.

**Step 6**

- Separate the empty sterile water vial and blue part from the clear part by unscrewing counter-clockwise

Step 7

- Draw air into the syringe by pulling the plunger to the required volume of sterile water added
- Connect the syringe to the clear part of the Mix2Vial
- Push the air in the syringe into the vial

**Step 8**

- Immediately invert the COAGADEX vial. The solution will be drawn into the syringe
- Disconnect the filled syringe from the device
- Use the product immediately or within one hour of reconstitution. Do not store the reconstituted product

Note: If there are any particles in the syringe, or if the solution is cloudy, or if a gel or clot forms, contact the manufacturer to report the batch number printed on the vial.

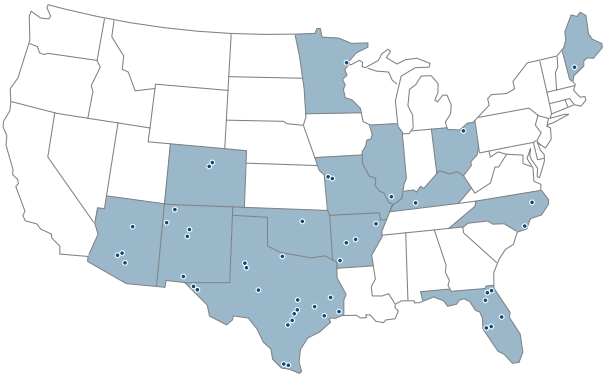
Call your healthcare provider or hemophilia treatment center if you experience any problems.

Who makes COAGADEX?

COAGADEX is made by Bio Products Laboratory (BPL), a leading supplier of blood protein therapies. BPL is based in the United Kingdom and has been making therapies from plasma (the liquid part of blood) for over 60 years.

All of the plasma used to make COAGADEX comes from collection centers owned and operated by BPL in the United States (US). Each center is inspected and approved by the US Food and Drug Administration (FDA).

BPL Plasma Collection Centers



For a list of BPL
Plasma Collection Centers, visit:
www.bplplasma.com

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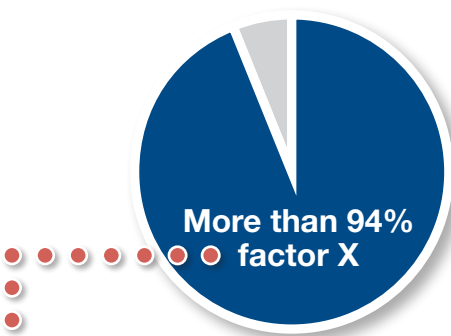
How is COAGADEX made?

COAGADEX is made from plasma donated by healthy individuals at licensed collection centers throughout the US.

- All donors undergo a thorough screening process for infections caused by viruses
- During processing, COAGADEX undergoes 3 separate steps specifically designed to remove or inactivate any viruses



COAGADEX is a high-purity product. It contains more than 94% factor X.



- With COAGADEX, you get the factor X you need without a lot of other proteins that you don't need.

Indications for COAGADEX

COAGADEX, a plasma-derived blood coagulation factor X concentrate, is indicated in adults and children with hereditary factor X deficiency for:

- Routine prophylaxis to reduce the frequency of bleeding episodes
- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding in patients with mild and moderate hereditary factor X deficiency

Limitation of Use

Perioperative management of bleeding in major surgery in patients with severe hereditary factor X deficiency has not been studied.

Important Safety Information for COAGADEX

COAGADEX is contraindicated in patients with known hypersensitivity to any of the components of the product.

Allergic type hypersensitivity reactions, including anaphylaxis, are possible with COAGADEX. If symptoms occur, patients should discontinue use of the product immediately, contact their physician, and administer appropriate treatment.

The formation of neutralizing antibodies (inhibitors) to factor X is a possible complication in the management of individuals with factor X deficiency. Carefully monitor patients taking COAGADEX for the development of inhibitors by appropriate clinical observations and laboratory tests.

COAGADEX is made from human plasma and may contain infectious agents, e.g. viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. No cases of transmission of viral diseases, vCJD or CJD, have been associated with the use of COAGADEX.

In clinical studies, the most common adverse reactions (frequency $\geq 5\%$ of subjects) with COAGADEX were infusion site erythema, infusion site pain, fatigue and back pain.

Please see full prescribing information in pocket.

Get help and support

Copay Assistance

If you have a prescription for COAGADEX and are having difficulty paying for your medication, BPL may be able to help.

- The COAGADEX Copay Support Program will provide up to \$12,000 per calendar year to cover out-of-pocket expenses for your COAGADEX prescription
- Some restrictions apply. To see if you qualify, visit [MyCoagadex.Medmonk.com](https://www.MyCoagadex.Medmonk.com)

Keep this card in your wallet. If you have a medical or dental procedure coming up, call the number on the back to make sure your hospital, doctor, or dentist has COAGADEX to treat any bleeding episode that may occur.

Ask BPL

BPL is committed to helping patients find answers to their questions about COAGADEX. This includes helping patients with:

- Copay assistance
- Issues with insurance coverage
- Prior authorizations and appeals
- Other questions related to COAGADEX



Call: 844-4BPLUSA (844-427-5872)



Email: Reimbursement@BPLgroup.com

**COAGADEX[®] ORDERING
INFORMATION LINE**

844-427-5872

Where can you go for additional information?

Hemophilia Treatment Centers

Hemophilia treatment centers (HTCs) were created specifically to meet the needs of patients with bleeding disorders. The members of the comprehensive care team at an HTC have the necessary experience to help patients manage all aspects of their condition.

Other Online Resources

To learn more about factor X deficiency, please visit these independent web sites:



National Hemophilia Foundation

www.hemophilia.org



Hemophilia Federation of America

www.hemophiliafed.org



World Federation of Hemophilia

www.wfh.org



LA KELLEY
communications, inc.

LA Kelley Communications

www.kelleycom.com

To learn more about COAGADEX,
visit www.coagadex.com

COAGADEX: The first and only treatment specifically for hereditary factor X deficiency

- **COAGADEX is a high-purity product** that contains 94% factor X
- **In clinical studies**, COAGADEX was proven effective for treating bleeds and reducing or preventing bleeds
- **In clinical studies, the most common adverse reactions with COAGADEX were infusion site erythema, back pain, fatigue, and infusion site pain**



For more information, and to request to speak to someone about COAGADEX, visit www.coagadex.com

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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See pages 17 and 18 of this brochure for a card to keep in your wallet.

If you have a medical or dental procedure coming up, call the number on the back to make sure your hospital, doctor, or dentist has COAGADEX to treat any bleeding episode that may occur.

References: 1. Austin S, Kavakli K, Norton M, et al. *Haemophilia*. 2016;22:419-425. 2. Liesner R, Akanezi C, Norton M, Payne J. *Haemophilia*. 2018 Apr 30. doi: 10.1111/hae.13500. [Epub ahead of print]

Coagadex[®]
Coagulation Factor X (Human)

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Bio Products Laboratory
a commitment for life

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please call 1-866-398-0825 or
email MedInfo@BPLgroup.com