**Package leaflet: Information for the patient**

**Coagadex 250 IU powder and solvent for solution for injection**
**Coagadex 500 IU powder and solvent for solution for injection**

human coagulation factor X

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**


## 1. What Coagadex is and what it is used for

Coagadex is a concentrate of human coagulation factor X, a protein that is needed for blood to clot. The factor X in Coagadex is extracted from human plasma (the liquid part of blood). It is used to treat and prevent bleeding in patients with hereditary factor X deficiency, including during surgery.

Patients with factor X deficiency do not have sufficient factor X for their blood to clot properly, leading to excessive bleeding. Coagadex replaces the missing factor X and allows their blood to clot normally.

## 2. What you need to know before you use Coagadex

**Do not use Coagadex:**
- if you are allergic to human coagulation factor X or any of the other ingredients of this medicine (listed in section 6).

Check with your doctor if you think this applies to you.

**Warnings and precautions**
Talk to your doctor, pharmacist or nurse before using Coagadex:

- if you have a larger or longer bleed than usual and the bleeding does not stop after an injection of Coagadex.
- if you are taking a medicine to prevent blood clotting that works by blocking clotting factor Xa. These medicines may prevent Coagadex from working.

Some patients with a shortage of factor X may develop inhibitors (antibodies) to factor X during treatment. This could mean that the treatment will not work properly. Your doctor will check regularly for the development of these antibodies, and especially before an operation. Both before and after treatment with this medicine, particularly for your first course of treatment, your doctor will probably carry out tests to check the level of factor X in your blood.

**Virus safety**
When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to recipients. These include:

– careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded,
– the testing of donated plasma for signs of virus/infections,
– the inclusion of steps in the processing of the blood or plasma that can inactivate or remove viruses.

The measures taken are considered effective for the following viruses: human immunodeficiency virus (HIV), hepatitis B virus, hepatitis C virus, hepatitis A virus and parvovirus B19. Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on an infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.

It is strongly recommended that every time you receive a dose of Coagadex, the name and batch number of the product are recorded in order to maintain a record of the batches used.

Your doctor may recommend that you consider vaccination against hepatitis A and B if you regularly or repeatedly receive human plasma-derived factor X products.

**Children and adolescents**
The listed warnings and precautions for adults also apply to children (aged 2 to 11 years) and adolescents (aged 12 to 18 years).

**Other medicines and Coagadex**
Tell your doctor if you are taking, have recently taken or might take any other medicines.

**Pregnancy, breast-feeding and fertility**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

**Driving and using machines**
There are no known effects of this medicine on the ability to drive or operate machinery.

**Coagadex contains sodium**
This medicine contains up to 9.2 mg sodium (the main component of cooking/table salt) in each millilitre of solution. This is equivalent to 0.0046% of the recommended maximum daily dietary intake of sodium for an adult.

## 3. How to use Coagadex

Your treatment should be initiated by a doctor who is experienced in the treatment of bleeding disorders.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Coagadex should be injected directly into a vein. Before injecting this medicine at home, you should have received training by your healthcare professional on how to do so.

Your doctor will explain to you how much you should use, when you should use it and for how long. Your doctor will usually tell you your dose in terms of the number of full vials that supply the dose most suited to you. Not more than 60 IU/kg daily should be administered in any age group.

**Use in adults**

**How much Coagadex is given to treat a bleed or prevent further bleeding?**
Your doctor will tell you how much Coagadex to administer to treat a bleed and to prevent further bleeding; the dose required will depend on your normal blood level of factor X

**How much is given before, during and after major surgery?**
**Before:** The dose of Coagadex used should be sufficient to raise your blood factor X level to between 70 and 90 units/dL. The dose you need will depend on your normal blood level of factor X and will be calculated by your doctor.

**After:** During the first few days after the operation, your plasma factor X concentration will be checked regularly. It is recommended that your blood factor X level is kept above 50 units/dL. The dose you need will be calculated by your doctor.

If your blood factor X concentration is too low (this will be tested by your doctor), or if it decreases faster than expected, an inhibitor to factor X may be present which stops the medicine from working properly. Your doctor will arrange for the appropriate laboratory tests to see if this is the case.

**How much is given regularly for long-term prevention of bleeds?**
Your doctor will advise if this use is suitable for you and, if so, of the appropriate dose.

**Use in children and adolescents**
Your doctor will recommend an appropriate dose for you or your child. Doses for children less than 12 years old are generally larger than for adolescents and adults. Doses for adolescents will be similar to those for adults.

**When to inject Coagadex**
- The medicine should be injected when the first sign of bleeding occurs.
- The injection should be repeated as necessary to stop the bleeding.
- Each individual bleed should be judged on its own severity.
- If you are using this medicine for the first time, your doctor will supervise you.

**Dissolving your medicines before use**
Your medicine must **only** be dissolved in the solvent provided with the product.

| Quantity of Coagadex | Volume of solvent |
|---|---|
| 250 IU | 2.5 mL |
| 500 IU | 5 mL |

Coagadex is supplied with the amount of solvent as shown in the table.

You can dissolve this medicine using the needle-free Mix2Vial transfer device included within each pack. Bring the containers of Coagadex to room temperature before mixing.
Make up the medicine as follows:

**Step 1**
• Remove the cap from the powder vial and clean the top of the stopper with an alcohol swab.
• Repeat this step with the vial of solvent.
• Peel back the top of the transfer device package but leave the device in the package.

**Step 2**
• Place the blue end of the transfer device on the solvent vial and push straight down until the spike penetrates the rubber stopper and snaps into place.
• Remove the plastic outer packaging from the transfer device and discard it, taking care not to touch the exposed end of the device.

**Step 3**
• Turn the solvent vial upside down with the device still attached.
• Place the clear end of the transfer device on the powder vial and push straight down until the spike penetrates the rubber stopper and snaps into place.

**Step 4**
• The solvent will be pulled into the powder vial by the vacuum contained within it.
• Gently swirl the vial to make sure the powder is thoroughly mixed. Do not shake the vial.
• A colourless, clear or slightly pearl-like solution should be obtained, usually in about 1 minute (5 minutes maximum).

**Step 5**
• Separate the empty solvent vial and blue part of the transfer device from the clear part by unscrewing anti-clockwise.
• Take an empty syringe (not provided in the Coagadex pack) and draw air into it by pulling the plunger to match the required volume of water added in step 4.
• Connect the syringe to the clear part of the transfer device and push the air in the syringe into the vial.

**Step 6**
• Immediately invert the vial of solution, which will be drawn into the syringe.
• Disconnect the filled syringe from the device.
• The product is now ready for use. Follow the normal safety practices for administration. Make sure you use the product within an hour after it has been made up.

Do not use this medicine:

- if the solvent is not pulled into the vial (this indicates loss of vacuum in the vial, so the powder must not be used).

- if the dissolved powder and solvent form a gel or a clot (if this happens please tell your healthcare provider, reporting the batch number printed on the vial).

**If you use more Coagadex than you should**
If you administer more of this medicine than your doctor prescribed, it is possible you might develop a blood clot. If you think you may be using too much, stop the injection and tell the doctor, pharmacist or nurse. If you know you have used too much, tell the doctor, pharmacist or nurse as soon as possible.

**If you forget to use Coagadex**
Do not use a double dose to make up for a forgotten dose. Inject your normal dose as you remember and then continue dosing as instructed by your doctor.

**If you stop using Coagadex**
Always consult your doctor before deciding to stop your treatment.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions (hypersensitivity reactions) have occurred rarely in the treatment of bleeding disorders with similar medicines (affecting up to 1 in 1,000 people), and sometimes progress to shock. Signs of these may include skin rash (including hives), tingling, flushing, nausea, vomiting, headache, cough, wheezing, tightness of the chest, chills, fast heart rate, dizziness, lethargy, restlessness, swelling of the face, tightness of the throat, discomfort at the site of injection.
If you get any of these contact your doctor.

The following side effects have been reported with Coagadex.

**Common (may affect up to 1 in 10 people):**
- pain or redness at site of injection
- tiredness
- back pain

**Side effects in children and adolescents**
Side effects in children are expected to be the same as in adults.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Coagadex

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the containers after "EXP". The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not freeze.

Keep container in the outer carton in order to protect it from light.

Do not use this medicine if you notice small bits in the dissolved product. Once made up, Coagadex must be used within one hour.

Do not throw away any medicines via wastewater or household waste. Your treatment centre will provide a special container to dispose of any solution that remains, any used syringes, needles and empty containers. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Coagadex contains**
- The active substance is human coagulation factor X. One vial contains nominally 250 IU or 500 IU human coagulation factor X.
- The other ingredients are: citric acid, disodium phosphate dihydrate, sodium chloride, sodium hydroxide and sucrose (see section 2 for further information about ingredients).
- Solvent: water for injections.

**What Coagadex looks like and contents of the pack**
Coagadex is a white or off-white powder and is packed in quantities of 250 IU and 500 IU. After being made up, the solution is colourless, clear or pearl-like (opalescent). Before injection, look at the solution. If the solution is cloudy or has any particles, do not use it.

A transfer device called Mix2Vial is also provided.

Contents of the 250 IU pack
1 vial 250 IU powder
1 vial 2.5 mL water for injections
1 Transfer Device (Mix2Vial)

Contents of the 500 IU pack
1 vial 500 IU powder
1 vial 5 mL water for injections
1 Transfer Device (Mix2Vial)

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
BPL Bioproducts Laboratory GmbH
Dornhofstraße 34, 63263 Neu-Isenburg
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**Manufacturer**
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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu