

Prothrombinex®-VF

Human prothrombin complex, powder for injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Prothrombinex®-VF. It does not contain complete information about Prothrombinex®-VF. It does not take the place of talking to your doctor.

If you have any concerns about using this medicine, please talk to your doctor. Follow your doctor's advice, even if it is different from what this leaflet says.

Please read this leaflet carefully and keep it for future reference.

The information in this leaflet is subject to change. Please check with your doctor if there is any new information about this medicine that you should know since you were last treated.

What Prothrombinex®-VF is used for

Prothrombinex®-VF contains the concentrated human coagulation factors II, IX and X and low levels of the factors V and VII. These are proteins which are essential for the normal blood clotting process. The coagulation factors II, VII, IX and X which are synthesised in the liver with the help of vitamin K, are commonly called the prothrombin complex. Individuals with coagulation factor levels lower than normal exhibit signs of difficulty in forming blood clots, with these clots often taking longer to be made than normal. Sometimes the individual may bleed unexpectedly into their joints, muscles or internal organs.

Prothrombinex®-VF is used in patients who require reversal of anticoagulant therapy and for the prevention and treatment of bleeding in patients with low levels of factor II, IX or X. It is not recommended for the management of patients with isolated factor V or factor VII deficiency.

Ask your doctor if you have any questions about why Prothrombinex®-VF has been prescribed for you.

Before you are given Prothrombinex®-VF

Prothrombinex®-VF must not be used if you:

- are allergic to one of the ingredients of this product
- are allergic to heparin
- have a history of heparin induced thrombocytopenia (low platelet count)
- have active thrombosis.

Tell your doctor if you have allergies to any other medicines or if you have ever had an allergic reaction to an injection.

Tell your doctor also if you:

- recently had a heart attack or have coronary artery disease
- have a history of thrombosis
- have a hereditary deficiency of any of the clotting factors
- are taking or using any other medicines. These include medicines bought from pharmacies, supermarkets and health food stores.
- have any other medical conditions
- are pregnant or breast-feeding
- become pregnant during your treatment.

If you want further information, consult your doctor.

About blood products

This product is made from human blood. When products are made from human blood and injected into you, it is possible that viruses or other substances could be present in the product and cause an illness. These could be viruses such as hepatitis, human immunodeficiency virus (HIV), or human parvovirus B19 and theoretically the Creutzfeldt-Jakob Disease (CJD) agent. There could also be other infectious agents some of which may not yet have been discovered.

To reduce the risk of this happening extra steps are taken when manufacturing this product. Strict controls are applied when selecting blood donors and donations. The product is specially treated to remove and kill viruses. These special treatments are considered effective against certain viruses known as enveloped viruses (such as HIV and hepatitis B and C) and also non-enveloped viruses, such as hepatitis A. These procedures may have some effect against the non-enveloped virus, parvovirus B19. Despite these measures, the risk of viral and other agents' infectivity cannot be totally eliminated.

Vaccines are available against some of these viruses and your doctor will be able to help you decide whether it is worthwhile having any of those vaccines.

Please discuss the risks and benefits of this medicine with your doctor.

How to use Prothrombinex®-VF

The dosage and administration of Prothrombinex®-VF must be carefully controlled. Your doctor will be responsible for determining what dose is appropriate to your condition. How much Prothrombinex®-VF you need and how long the therapy lasts will depend on your situation.

Prothrombinex®-VF will usually be given in a hospital. Should your doctor decide that treatment at home is appropriate, they will provide detailed instructions on how to use Prothrombinex®-VF.

Side effects

Along with their intended effects, medicines may cause some unwanted effects, which can sometimes be serious. Furthermore, individual patients may react differently to the same dose of the same medicine. This applies to Prothrombinex®-VF.

Although severe reactions after Prothrombinex®-VF injection are rare, heart attacks and blood clots (thromboses) have occurred during treatment with Prothrombinex®-VF. Ask your doctor if you need more information.

If you experience any of the following side effects during the administration of Prothrombinex®-VF, tell your doctor immediately:

- fever
- chills
- dizziness, nausea or vomiting
- itching
- rash
- tightness of the chest
- wheezing or breathlessness.

Other possible unwanted effects include inflammation of veins, headache, pain and drowsiness. Lowering of blood platelets (thrombocytopenia) may sometimes occur due to a constituent in the formulation (heparin sodium).

Overdose

Overdosage may enhance the risk of heart attacks and blood clots (thrombosis). If you have questions, consult your doctor.

Storing Prothrombinex®-VF

Store at 2°C to 8°C (Refrigerate. Do not freeze). Prothrombinex®-VF can be stored below 25°C for a single period of 6 months. The product must not be returned to refrigeration after storage below 25°C. Protect from light. Prothrombinex®-VF must not be used after the expiry date printed on the label.

Further information

This is not all the information that is available on Prothrombinex®-VF. If you have any more questions or are not sure about anything, ask your doctor.

Product description

What it looks like

Prothrombinex®-VF is a white powder contained in a glass vial. The product comes with a vial of Water for Injections for reconstitution, and a special filter transfer set called a Mix2Vial™.

Ingredients

Each vial of Prothrombinex®-VF contains 500 IU of factor IX, approximately 500 IU each of factors II and X. It also contains 25 IU of antithrombin III and 192 IU of heparin sodium. Other ingredients include ≤500 mg of human plasma proteins (which includes low levels of factors V and VII), sodium citrate, sodium phosphate and sodium chloride. The factors II, IX, X, the antithrombin III and the plasma proteins are all of human origin. The heparin sodium is of porcine origin.

Manufacturer

Prothrombinex®-VF is manufactured in Australia by:

CSL Behring (Australia) Pty Ltd
ABN 48 160 734 761
189-209 Camp Road
Broadmeadows VIC 3047
Australia

Distributor

Australian Red Cross Blood Service

Date of most recent amendment

August 2014

Australian Register Number

AUST R 124381

® Registered trademark of CSL Limited

Mix2Vial™ is a trademark of West Pharmaceutical Services, Inc. or a subsidiary thereof.