What adverse effects might occur?

Adverse effects are uncommon or rare.

- An allergy to a protein in the product occurs rarely. It will be necessary to stop or modify the treatment if this occurs.
- As these products are made from blood donations a virus infection could possibly be transmitted. There is further information on this in the section on “Safety of coagulation factor concentrates”.
- Prothrombinex™-VF and similar products have rarely been associated with thrombosis (abnormal clotting in blood vessels). Prothrombinex™-VF contains substances to inhibit thrombosis and is injected slowly to minimise this risk.

Do coagulation factor concentrates ever fail to give the expected results?

- If the dose injected is too small, bleeding may not stop completely.
- About 10% to 15% of people with haemophilia develop an antibody against the injected clotting factor, called an inhibitor. Inhibitors interfere with the action of the clotting factor, and can lead to a poor response to clotting factor treatment and serious bleeding problems in some people.
- Inhibitors will usually appear during the first 50 doses of treatment, if they are going to appear. Special tolerisation treatment which attempts to reverse this problem may be available for some children.

Safety of coagulation factor concentrates

Because plasma-derived coagulation factor concentrates are blood products they could possibly pass on some infections.

- Important infections such as HIV/AIDS, hepatitis B and hepatitis C have never been reported to be spread by the coagulation factor concentrates described in this leaflet.
- Parvovirus B19 is a common virus in the community. Rare cases have been reported where this virus has been spread by clotting factor concentrates similar to Prothrombinex™-VF. Parvovirus B19 can cause a mild “flu-like” illness, with a skin rash, joint pains and a brief reduction in the production of red blood cells by the bone marrow. These problems are usually very minor and of short duration, but may rarely be severe. There is a small chance that some viral infections caused by parvoviruses and other similar viruses could be passed on by Prothrombinex™-VF. Biostate® and MonoFIX®-VF is treated to reduce these risks even further.
- Blood donations are only collected from donors who are in good health and do not have any condition identifiable by the standard donor checks, that could be passed on to someone receiving a coagulation factor concentrate.
- Every blood donation is tested for the infections: HIV/AIDS, syphilis, hepatitis B and C. Blood donations are only used if the tests show no evidence that these infections are present.
- The manufacturing processes for making coagulation factor concentrates are able to destroy the above viruses, as well as many others.
- There is no evidence that CJD (Creutzfeld-Jakob Disease), or variant CJD, has ever been passed on by blood products manufactured from New Zealand plasma.

What are recombinant clotting factors?

The coagulation factor concentrates described in this leaflet are made from the blood donations of voluntary New Zealand blood donors by CSL Behring, Melbourne, Australia.

Some blood clotting factor concentrates are made by a semisynthetic process using recombinant DNA technology. Recombinant DNA products are not discussed in this leaflet.

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Blood Coagulation Factor Concentrates

INFORMATION

Your guide to blood transfusion

You have been given this leaflet because your Doctor considers you may need treatment with Coagulation Factor Concentrates.

As with any treatment you have the right to decide whether you want to have the treatment or not. You will be asked to sign a Consent Form to show that:

- the benefits, risks and alternatives for your treatment, including transfusion of blood products, have been explained to you,
- you have been able to ask any questions about the treatment, and
- you agree to receive the treatment.

This leaflet provides information to assist with informed consent for treatment with one of the following blood coagulation (clotting) factor products:

- **Biostate® (Factor VIII)**
- **Prothrombinex™-VF (Factors II, IX & X)**
- **MonoFIX®-VF (Factor IX)**

What are blood clotting factors?

- Blood clotting factors are natural proteins in the blood. Most are made in the liver.
- They are needed to help stop bleeding. If blood clotting factor levels in blood are low, blood will clot more slowly and clots will be weaker.
- A low level of clotting factors will cause a bleeding tendency. The severity of bleeding will depend on the level of clotting factors present.

What are the expected benefits from coagulation factor concentrates?

- Bleeding will stop and further bleeding will be prevented.

How does the body stop bleeding?

Bleeding will occur when blood vessels are injured. The body stops bleeding by several mechanisms that work together. The diagram below shows how this happens:

- **Blood vessels** contract and slow the bleeding.
- **Platelets** are tiny particles in the blood that quickly form a plug to stop bleeding from small blood vessels. The clotting protein von Willebrand factor is needed to help platelets form a platelet plug and stop bleeding.
- **Blood coagulation (clotting)** occurs slowly over 5 to 15 minutes. Coagulation involves several other clotting proteins, including Factor VIII and Factor IX. It results in a tough clot that reinforces the platelet plug. Blood clotting is essential so that bleeding doesn't start again and so that tissue injuries can be repaired.

How bleeding is stopped

Stage 1 involves blood vessels contracting and activation of platelets. Platelets from blood stick rapidly to the injured blood vessel and form a platelet plug.

von Willebrand factor is needed at this stage.

Stage 2 involves blood coagulation (clotting) and normally takes 5-15 minutes. A clot is a fibrous mesh that is anchored in nearby tissues and reinforces the platelet plug. It ensures bleeding does not easily start again.

The support organisation for people in New Zealand with Haemophilia is:

Haemophilia Foundation of New Zealand
Free phone: 0508 FACTOR - 0508 322 867
Fax: 03 344 5206
Email: info@haemophilia.org.nz
Internet: www.haemophilia.org.nz

What Coagulation factor concentrates are available?

Biostate® (Factor VIII) – introduced in NZ 2005.

This product contains coagulation Factor VIII and von Willebrand factor. It can be used to treat:

- Haemophilia A – inherited deficiency of Factor VIII.
- Acquired haemophilia A – due to an antibody that blocks activity of Factor VIII.
- von Willebrand disease – low levels of von Willebrand factor – needed by platelets.

Biostate® is a high purity form of Factor VIII.

The manufacturing process includes solvent-detergent treatment and heating to 80°C for 72 hours to inactivate hepatitis B, hepatitis C, HIV/AIDS and many other viruses.

Prothrombinex™–VF – used in NZ since 2007.

This product contains coagulation Factors II, IX and X. It is used to treat:

- Haemophilia B – inherited deficiency of Factor IX.
- Occasionally it may be used to treat bleeding due to an overdose of the anti-clotting medicine warfarin.
- Rarely it may be needed to treat people with deficiencies of Factors II or X.

Prothrombinex™-VF is heated at 80°C for 72 hours followed by a viral filtration step. These processes inactivate hepatitis B, hepatitis C, HIV/AIDS and many other viruses.

MonoFIX®-VF – introduced in 1999.

MonoFIX®-VF is a highly purified form of Factor IX. It is used to treat:

- Haemophilia B – inherited deficiency of Factor IX.

The manufacturing process includes solvent-detergent and special filtration steps to destroy or remove small viruses.