

Beriplex[®] NZ

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given Beriplex[®] NZ?

Beriplex[®] NZ contains the active ingredients, human coagulation factor II, factor VII, factor IX and factor X, proteins C and S. Beriplex[®] NZ is used to treat bleeding conditions that may be caused when you are taking a blood thinner (e.g. warfarin) and unexpected bleeding occurs.

For more information, see Section [1. Why am I being given Beriplex[®] NZ?](#) in the full CMI.

2. What should I know before I am given Beriplex[®] NZ?

Do not use if you have ever had an allergic reaction to Beriplex[®] NZ or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding or are on a sodium controlled diet.

For more information, see Section [2. What should I know before I am given Beriplex[®] NZ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Beriplex[®] NZ and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given Beriplex[®] NZ?

- Your doctor will decide what dose is best for your particular situation or condition.

More instructions can be found in Section [4. How will I be given Beriplex[®] NZ?](#) in the full CMI.

5. What should I know after I am given Beriplex[®] NZ?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Beriplex[®] NZ.
Things you should not do	• Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
Driving or using machines	• No studies on the effects on the ability to drive and use machines have been performed.
Looking after your medicine	• Store Beriplex[®] NZ below 25°C. Do not freeze. Keep the vial in the outer carton, in order to protect from light. • Do not use after the expiry date.

For more information, see Section [5. What should I know after I am given Beriplex[®] NZ?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Beriplex[®] NZ

Active ingredients: *human coagulation factor II, factor VII, factor IX and factor X, proteins C and S.*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Beriplex[®] NZ. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Beriplex[®] NZ.**

Where to find information in this leaflet:

- [1. Why am I being given Beriplex[®] NZ?](#)
- [2. What should I know before I am given Beriplex[®] NZ?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Beriplex[®] NZ?](#)
- [5. What should I know after I am given Beriplex[®] NZ?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given Beriplex[®] NZ?

Beriplex[®] NZ contains the active ingredients human coagulation factor II, factor VII, factor IX and factor X, proteins C and S. The active ingredients in Beriplex[®] NZ are made from human plasma (the liquid component of blood) collected by the New Zealand Blood Service, whilst some of the inactive ingredients are manufactured from human plasma collected overseas.

Beriplex[®] NZ is used to treat bleeding conditions that may be caused when you are taking a blood thinner (e.g. warfarin) and unexpected bleeding occurs.

The coagulation factors called factor II, factor VII, factor IX and factor X together make up the prothrombin complex. The factors are made in the liver when your body has enough vitamin K.

Medicines, like warfarin, which are used to thin the blood (also called vitamin K antagonists, or anticoagulants) prevent blood clotting and may work by stopping the liver from making coagulation factors.

If you do not have enough vitamin K, or you have been treated with medicines which are used to thin the blood, you may be at risk of bleeding and haemorrhage.

Beriplex[®] NZ works by replacing the coagulation (clotting) factors your body needs.

Beriplex[®] NZ belongs to a group of medicines called prothrombin complex products, which are made from human blood.

2. What should I know before I am given Beriplex[®] NZ?

Warnings

You must not be given Beriplex[®] NZ if:

- you are allergic to human coagulation factor II, factor VII, factor IX and factor X, proteins C and S, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have an increased risk of forming blood clots.
- you are allergic to a medicine called heparin (used to thin the blood and prevent clots).

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - a heart condition (e.g. angina, or a recent heart attack)
 - liver disease
 - a bleeding disorder.
- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- have recently had surgery or a blood transfusion.
- have had blood clots in a blood vessel (e.g. deep vein thrombosis).
- are taking or using any other medicines.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

During pregnancy and breastfeeding Beriplex[®] NZ should be given only if it is clearly indicated.

Virus safety

Beriplex[®] NZ is made from human plasma (the liquid component of blood). When medicines are made from human blood and injected into you, it is possible that viruses or other substances could be present in the medicine and cause an illness. These could be viruses such as hepatitis, human immunodeficiency virus (HIV), or human parvovirus B19 and theoretically 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 medicine. Strict controls are applied when selecting blood donors and donations. The medicine is specially treated to remove and kill certain viruses. This special treatment is considered effective against certain viruses known as enveloped viruses such as HIV, hepatitis B and hepatitis C viruses, and the non-enveloped viruses hepatitis A and parvovirus B19.

Despite these measures, the risk of viral and other agent's 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 risk and benefits of this product with your doctor.

Beriplex® NZ contains sodium

Beriplex® NZ contains up to 343 mg sodium (approximately 15 mmol) per 100 mL. Please take this into account if you are on a sodium controlled diet.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may affect the way other medicines work.

Beriplex® NZ may prevent the effects of medicines which cause blood thinning (called anticoagulants).

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Beriplex® NZ.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Beriplex® NZ.

4. How will I be given Beriplex® NZ?

How much will I be given

- The amount of Factor II, VII, IX, and X you need and the duration of treatment will depend on several factors, such as your body weight, the severity and nature of your disease, the site and intensity of the bleeding or the need to prevent bleeding during an operation or investigation.

When will Beriplex® NZ be given

Treatment should be started and supervised by a doctor who is experienced in this type of disorder.

Beriplex® NZ would usually be given in a hospital, in an emergency situation.

If too much Beriplex® NZ is given

Your doctor should regularly check your blood clotting status during the treatment. High doses of prothrombin

complex concentrate have been associated with instances of heart attack, disseminated intravascular coagulation and an increased formation of blood clots in blood vessel in patients at risk of these complications.

5. What should I know after I am given Beriplex® NZ?

Things you should do

Call your doctor straight away if you:

notice:

- difficulty breathing,
- flushing,
- dizziness, or
- tightness of the chest

while you are being given Beriplex® NZ or afterwards.

These may be signs of a serious allergy or anaphylaxis.

If you are about to be started on any new medicine tell your doctor and pharmacist that you have had Beriplex® NZ.

Remind any doctor, dentist or pharmacist you visit that you have been given Beriplex® NZ.

Things you should not do

- Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

Driving or using machines

No studies on the effects on the ability to drive and use machines have been performed.

Be careful before you drive or use any machines or tools until you know how Beriplex® NZ affects you.

Looking after your medicine

- Store Beriplex® NZ below 25°C. Do not freeze.
- Keep the vial in the outer carton, in order to protect from light.
- Keep this medicine out of the sight and reach of children.
- Beriplex® NZ does not contain a preservative so the made-up solution should preferably be used immediately.

Follow the instructions in the carton on how to take care of your medicine properly.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• burning, stinging, redness or bruising where the injection was given • skin rash • headache • restlessness • tingling • tiredness.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
• skin rash over the whole body • flushing • chills • hives • feeling faint • nausea or vomiting • faster heart beat • tightness of the chest • wheezing.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Beriplex® NZ is not addictive.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the New Zealand Pharmacovigilance Centre online at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

Beriplex® NZ is usually given in a hospital.

What Beriplex® NZ contains

Active ingredients (main ingredients)	Human coagulation factor II, Factor VII, Factor IX, Factor X, Proteins C and S
Other ingredients (inactive ingredients)	Beriplex® NZ does not contain preservatives, however it does contain other materials that keep it stable. These ingredients are: Antithrombin III (human) Albumin (human) Heparin sodium (porcine) Sodium chloride Sodium citrate

Do not take this medicine if you are allergic to any of these ingredients.

What Beriplex® NZ looks like

Beriplex® NZ is presented as a white or slightly coloured powder and is supplied with water for injection as solvent.

Beriplex® NZ comes as a pack which contains:

- a vial of product (Beriplex® NZ) which is a white or slightly coloured powder
- a Mix2Vial™ filter transfer set in a blister
- a vial of diluent (Water for Injections) to dissolve the powder.

Sponsor details

Beriplex® NZ is supplied in New Zealand by:

CSL Behring (NZ) Limited

PO Box 62590

Greenlane

Auckland 1546

NEW ZEALAND

0800 640 677

Distributor

New Zealand Blood Service

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