

BERIPLEX[®] P/N

Human prothrombin complex

Consumer Medicine Information

250 IU: AUST R 156330

500 IU: AUST R 156459

1000 IU: AUST R 228338

What is in this leaflet

This leaflet answers some common questions about Beriplex[®] P/N.

The leaflet does not contain all the available information.

It does not take the place of talking to your doctor.

All medicines have benefits and risks. Your doctor has weighed the benefits that Beriplex[®] P/N will have for you against the risks.

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

Keep this leaflet with the medicine. You may need to read it again.

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

What Beriplex[®] P/N is used for

Beriplex[®] P/N 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.

Ask your doctor if you have any questions about why Beriplex[®] P/N has been prescribed for you.

How Beriplex[®] P/N works

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

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

Before you are given Beriplex[®] P/N

When you must not receive it

You should not be given Beriplex[®] P/N if:

- you have an allergy to Beriplex[®] P/N or any of the ingredients listed at the end of this leaflet
- 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).

If you are not sure whether you should be given Beriplex[®] P/N talk to your doctor.

Before you are given it

Tell your doctor if you:

1. Are pregnant or breast feeding, or become pregnant during your treatment.
2. Have any other medical conditions, especially the following:
 - a heart condition (e.g. angina, or a recent heart attack)
 - liver disease
 - a bleeding disorder.
3. Have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
4. Have recently had surgery or a blood transfusion.
5. Have had blood clots in a blood vessel (e.g. deep vein thrombosis).
6. Are taking or using any other medicines.

If you have not told your doctor about any of the above, tell them before you are given any Beriplex[®] P/N.

If you want further information, consult your doctor.

About blood products

Beriplex[®] P/N 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 risks and benefits of this product with your doctor.

Taking other medicines

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

Beriplex[®] P/N may prevent the effects of medicines which cause blood thinning (called anti-coagulants).

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Beriplex[®] P/N.

How Beriplex[®] P/N is given

How much will be used

You would usually be given Beriplex[®] P/N in a hospital, in an emergency situation.

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

When you have been given Beriplex® P/N

Things you must do

If you notice:

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

while you are being given Beriplex® P/N or afterwards, tell your doctor immediately. 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® P/N.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are being given Beriplex® P/N.

Beriplex® P/N helps most people, but it may have unwanted side effects in a few people. 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.

Tell your doctor if you notice any of the following and they worry you:

- burning, stinging, redness or bruising where the injection was given
- skin rash
- headache
- restlessness
- tingling
- tiredness.

These are the more common side effects of Beriplex® P/N and occur very rarely.

Sometimes a side effect may be serious. Tell your doctor immediately if you notice any of the following:

- skin rash over the whole body
- flushing
- chills
- hives
- feeling faint
- nausea or vomiting
- faster heart beat
- tightness of the chest
- wheezing.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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

Beriplex® P/N is not addictive.

Storing Beriplex® P/N

Store Beriplex® P/N 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.

Product description

What Beriplex® P/N looks like

Beriplex® P/N comes as a pack which contains:

- a vial of product (Beriplex® P/N) 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.

Ingredients

Active ingredients

The active ingredients are human coagulation factor II, factor VII, factor IX and factor X, proteins C and S.

Inactive ingredients

Beriplex® P/N 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.

Date of revision

January 2022

® Registered trademark of CSL Limited Group of Companies

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

Further information

This leaflet does not contain all the available information about Beriplex® P/N. If you require further information about Beriplex® P/N and your treatment generally, or if you have any questions or are not sure about something in this leaflet, consult your doctor.

Sponsor

In Australia

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

In New Zealand

CSL Behring (NZ) Limited
P O Box 62590
Greenlane
Auckland 1546
New Zealand

Manufacturer

CSL Behring GmbH
35041 Marburg
Germany