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Blood thinner reversals

If you have atrial fibrillation (AFib) and are taking a blood thinner, you're likely doing so to help prevent a stroke. You may also know that your risk of bleeding may be increased if you are seriously injured or require urgent surgery. But did you know that some blood thinner medications have treatments that doctors can use to temporarily reverse the blood-thinning effects in an emergency?

In the event that something unexpected happens – like a bad fall, a serious illness or accident – which might require urgent / immediate care or surgery, having the peace of mind to know the effects of your blood thinner can be reversed is something to consider. Discuss your options with your healthcare professional.

AFib is the most common type of irregular heartbeat that can lead to severe and debilitating strokes. According to Canadian clinical guidelines, blood thinners (also known as anticoagulants) are recommended for AFib patients to reduce their risk of stroke.

Life is unpredictable, and you never know when you may need to quickly reverse the effects of your blood thinner. Receiving stroke prevention treatment with a blood thinner drug that has reversal agents may be well worth a discussion with your doctor.

Questions to Ask Your Healthcare Professional:

- Is the blood thinner I'm on the most appropriate for me to protect me from stroke?
- What kind of situations would require the use of a treatment that would reverse the effects of my blood thinner?
- Are there treatments available to temporarily reverse the effects of my blood thinner?

How to reverse the effects of certain blood thinners

Blood thinners (anticoagulants) work to help reduce your risk of stroke in atrial fibrillation (AFib). But did you know that you might need to temporarily reverse its blood thinning effects in an emergency?

Below are medications that a doctor can use to reverse the effects of Pradaxa® and Coumadin® (warfarin).

Praxbind™

Blood thinner reversal for Pradaxa® (formerly branded as Pradax® in Canada)

What it does

Praxbind™ is used for emergency situations where a doctor decides that rapid reversal of the effect of Pradaxa® is required:

- Emergency surgery/urgent procedures
- Life-threatening or uncontrolled bleeding

Once in the blood stream, Praxbind™ binds to Pradaxa®, reversing its anti-clotting effect. 24 hours after administering Praxbind™, re-administration of Pradaxa® may be considered by your doctor.

Precautions

Praxbind™ will only work for reversal of Pradaxa®. It will not reverse other medicines used to prevent the formation of blood clots.

Use with Other Medications

Tell your healthcare professional about all the medicines you take, including any prescription or non-prescription drugs, vitamins, minerals, natural supplements or alternative medicines. Praxbind™ should not be used if you are allergic (hypersensitive) to idarucizumab or to any of the other non-medicinal ingredients of Praxbind™.

Preclinical studies have shown no interactions of Praxbind™ with volume expanders, coagulation factor concentrates and anticoagulants other than Pradaxa®.

Based on the properties and the high specificity in binding to Pradaxa®, clinically relevant interactions with other medicinal products are considered unlikely.

Possible Side Effects

If you experience any side effects such as hypersensitivity or allergic reaction symptoms, after Praxbind™ administration, inform your healthcare professional.

If you have a troublesome symptom or side effect after Praxbind™ administration which becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

In studies of very sick patients mild symptoms of potential hypersensitivity (fever, difficulty in breathing or wheezing, increased frequency of rapid breathing, rash or itching) were also reported in these patients. Further adverse events, reported in greater than or equal to 5% of patients, were low blood levels of potassium (7%), acute confusional state (7%), difficulty passing stools (7%), fever (6%), and lung infection (6%). These were reported in a clinical trial, but may not be directly related to Praxbind™.

Octaplex®

(Human Prothrombin Complex, freeze dried)

(Powder and solvent for solution for injection)

Blood thinner reversal for Coumadin[®](warfarin)

What it does

The administration of Octaplex[®] can temporarily stop bleeding in patients with deficiency of one or several of the coagulation factors II, VII, IX and X, which are commonly called the Prothrombin Complex. Such a deficiency can be caused by vitamin K antagonists (e.g. warfarin/Coumadin[®]). Octaplex[®] will start working immediately upon injection. Octaplex[®] should only be used when rapid correction of major bleeding or emergency surgery is warranted.

When it should not be used

- If reduction of the dose of the vitamin K antagonist and/or administration of vitamin K is sufficient.
- **Octaplex[®] is not for patients who are hypersensitive to this drug or to any ingredient in the formulation, such as heparin, or component of the container.**
- Octaplex[®] should not be used in patients with a recent heart attack, with a high risk of blood clots, or with coronary artery disease, or chronic liver disease.

Precautions

This product is made from human plasma, which may contain hepatitis and other viral diseases. Your doctor should discuss the risks and benefits of this product with you before giving you this product.

Before you use Octaplex[®] talk to your doctor or pharmacist if:

- You recently had a heart attack, have a high risk of blood clots, or have coronary artery disease, or liver disease
- You are predisposed to allergies. Antihistamines and corticosteroids may be given prior to receiving this drug
- You have not received appropriate vaccinations for hepatitis A and B. These vaccinations should be considered if You will be receiving regular/repeated treatments with this drug
- You are allergic against heparin
- You are pregnant or nursing. A pregnancy test is recommended before receiving Octaplex[®]
- You will be undergoing any scheduled surgical procedures
- You are allergic to the active substance or to any of the nonmedicinal ingredients

Possible Side Effects

Side effects may include:

- Headaches may rarely occur.
- Allergic or allergic-type reactions: early signs include hives, increase in body temperature, generalized hives, tightness of the chest, wheezing, hypotension, and anaphylaxis. If allergic symptoms occur, discontinue the administration immediately and contact your physician. In case of shock, the current medical standards for treatment of shock are to be observed. No case of allergic or anaphylactic reaction was reported under Octaplex[®] treatment so far; therefore the incidence is expected to be very low.
- Immune system disorders: Replacement therapy may rarely lead to the formation of circulating antibodies inhibiting one or more of the human prothrombin complex factors. If such inhibitors occur, the condition will manifest itself as a poor clinical response. A final statement on the development of inhibitors in

previously treated patients cannot be made. This is not a complete list of side effects. For any unexpected effects while taking Octaplex[®], contact your doctor or pharmacist.

Beriplex[®]P/N 500 / Beriplex[®]P/N 1000

(Powder and solvent for solution for injection)

(Human Prothrombin Complex)

Blood thinner reversal for Coumadin[®](warfarin)

What it does

In normal individuals, damage to blood vessels trigger a cascade of events that activate specific proteins present in their blood and which are responsible for the formation of a clot that ultimately stops the bleeding.

In patients treated with vitamin K antagonists (e.g. warfarin, Coumadin[®], etc., or heparins), damage to blood vessels does not trigger the full cascade of events leading to the formation of blood clots.

Beriplex[®]P/N is used to treat or prevent bleeding in these patients by providing adequate amounts of the necessary missing or inhibited factors required for normal blood coagulation.

When it should not be used

Beriplex[®]P/N should not be used if you are experiencing any of the following:

- Hypersensitivity to the active substance or to any of the excipients listed in section Dosage Forms, Composition and Packaging
- Disseminated intravascular coagulation
- Known history of heparin-induced thrombocytopenia

Precautions

The use of prothrombin complex concentrates is associated with the risk of thrombosis. Cases of thrombosis have been observed in conjunction with treatment with Beriplex[®]P/N.

Before you use Beriplex[®]P/N talk to your doctor or pharmacist if:

- You are on a controlled sodium diet
- You have a history of coronary heart disease, myocardial infarction, liver disease, are at risk for thromboembolic phenomena or disseminated intravascular coagulation, or have simultaneous inhibitor deficiency
- You are breastfeeding, pregnant or trying to become pregnant
- Have recently undergone surgery
- Are allergic to Beriplex[®]P/N, its ingredients or the components of its container
- You are receiving vitamin K antagonists
- You have a history of acquired or congenital deficiency of the vitamin K-dependent coagulation factors
- You have a history of heparin-induced thrombocytopenia

Use with Other Medications

Beriplex[®]P/N neutralizes the effects of vitamin K1 antagonist treatments.

Possible Side Effects

A doctor should be called immediately if any of these reactions occurs:

- Tissue and abdomen swelling from excess salt and fluid retention, frothy urine (nephrotic syndrome);
- Thromboembolic episodes;
- Increase in body temperature;
- Hypersensitivity or allergic reactions (which may include angioedema, burning / stinging at the injection site, chills, flushing, generalized urticaria, headache, hives, hypotension, lethargy, nausea, restlessness, tachycardia, angina pectoris, tingling, vomiting or wheezing);
- Small blood clots or excessive bleeding due to depleted clotting factors (disseminated intravascular coagulation);
- Anaphylactic reactions including anaphylactic shock
- Development of antibodies to one or several factors of the prothrombin complex;
- Multiple purple pinpoint bruises, easy bruising, unusually heavy menstruation (could be caused by heparin-induced thrombocytopenia, type II).

Your doctor will decide whether it is appropriate or not to discontinue the treatment with Beriplex[®]P/N.

This is not a complete list of side effects. For any unexpected effects while taking Beriplex[®]P/N, contact your doctor or pharmacist.

Vitamin K1

Phytonadione

Hypoprothrombinemia Therapy

If you have been diagnosed with AFib, act now! Talk to your doctor about how to help reduce your stroke risk today. Only you and your doctor can determine the treatment plan that is right for you.

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