PART III: CONSUMER INFORMATION

octaplex®
Human Prothrombin Complex

This leaflet is part III of a three-part "Product Monograph" published when octaplex® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about octaplex®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- Treatment of bleeding and perioperative prophylaxis of bleeding in acquired deficiency of the prothrombin complex coagulation factors, such as deficiency caused by treatment with vitamin K antagonists, or in case of overdose of vitamin K antagonists, when rapid correction of the deficiency is required.

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. 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.

What the medicinal ingredients are:
Human Coagulation Factor II, VII, IX and X, and Proteins C and S.

What the important nonmedicinal ingredients are:
Heparin, sodium citrate, solvent (Water for Injection)

What dosage forms it comes in:
Powder and solvent for solution for injection. One package of octaplex® contains:
One powder vial containing the active ingredients (coagulation factors) and excipients, a second vial containing 20 ml/ 40 ml of diluent and a Mix2Vial™ transfer set with integrated filter.

WARNINGS AND PRECAUTIONS

Serious Warnings and 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 (see WARNINGS AND PRECAUTIONS - General).

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.

INTERACTIONS WITH THIS MEDICATION

There is no known drug interaction to octaplex®. Components used in the packaging of octaplex® are latex-free.

PROPER USE OF THIS MEDICATION

Usual dose:
The dose you receive depends on your test results for prothrombin complex levels and your body weight. The dose will be given intravenously at an initial rate of 1 ml per minute and increasing to no faster than 2 – 3 ml per minute.

Overdose:
No symptoms of overdose with octaplex® have been reported.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
Acquired deficiencies:
Not applicable because in acquired deficiencies octaplex® is administered in a hospital setting by health care professionals.

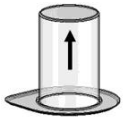
Administration
octaplex® should be administered under the supervision of a qualified health professional.
octaplex® should be administered intravenously. Please read all the instructions and follow them carefully. During the procedure described below, aseptic technique must be maintained. The product reconstitutes quickly at room temperature. The solution

should be colourless to slightly blue. Do not use solutions that are cloudy or have deposits. Reconstituted products should be inspected visually for particulate matter and discolouration prior to administration. A blue colour is not interpreted as discolouration.

Instructions for Reconstitution:

Fig. 1

1. If the octaplex® powder and water for injection (WFI) are not already at room temperature, warm up the closed vials to room temperature (maximum 37°C). This temperature should be maintained during reconstitution. If a water bath is used to warm the WFI, care should be taken to ensure the water does not come into contact with the rubber stopper or closure system of the vials.



2. Remove the flip caps from the octaplex® vial and the WFI vial and clean the rubber stoppers with an alcohol swab.

Fig. 2

3. Peel away the lid of the outer package of the Mix2Vial™ transfer set. Place the WFI vial on an even surface and hold the vial firmly. Take the Mix2Vial™ together with its outer package and invert it. Push the blue plastic cannula of the Mix2Vial™ firmly through the rubber stopper of the WFI vial in one swift motion (Fig. 1). While holding onto the WFI vial, carefully remove the outer package from the Mix2Vial™, being careful to leave the Mix2Vial™ attached firmly to the WFI vial (Fig. 2).

4. With the octaplex® vial held firmly on an even surface, quickly invert the WFI vial (with the Mix2Vial™ attached), push the transparent plastic cannula end of the Mix2Vial™ firmly through the stopper of the octaplex® vial, and hold the downward pressure (Fig. 3). The WFI will be drawn into the octaplex® vial by vacuum.

Fig. 3

Fig. 4

5. With both vials still attached, slowly rotate the octaplex® vial to ensure the product is fully dissolved to a clear or slightly opalescent solution. Once the contents of the octaplex® vial are dissolved, firmly hold both the transparent and blue parts of the Mix2Vial™. Unscrew the Mix2Vial™ into two separate pieces with the vials still attached (Fig. 4) and discard the empty WFI vial and the blue part of the Mix2Vial™.

Instructions for Injection:

As a precautionary measure, the patient's pulse rate should be measured before and during the injection. If a marked increase in the pulse rate occurs, the injection speed must be reduced or the administration must be interrupted.

1. After octaplex® has been reconstituted, attach a plastic sterile disposable syringe to the transparent part of Mix2Vial™. Invert the system and draw the reconstituted octaplex® into the syringe.
2. Once the octaplex® solution has been transferred into the syringe, firmly hold the barrel of the syringe (keeping it facing down) and detach the Mix2Vial™ from the syringe. Discard the Mix2Vial™ (transparent plastic part) and the empty octaplex® vial.
3. Disinfect the injection site with an alcohol swab and attach the syringe to a suitable infusion needle. Alternatively, octaplex® can be administered using an IV line. Ideally, a new, clean IV line should be used. Otherwise, the IV line must first be 'cleaned' of other products by flushing it with a saline or dextrose 5% solution. octaplex® should not be mixed with any other product (including saline or dextrose 5% solution) in the IV line.
4. Using an aseptic technique, inject the octaplex® solution intravenously at an initial rate of 1 ml per minute, followed by 2-3 ml per minute, if appropriate. A pump can be used to regulate and control the injection rate when administering octaplex®.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- Allergic or allergic-type reactions: early signs include hives, swelling of the face or tongue, , injection site reactions, chills, rapid reddening of neck/ facial region, headache, tightness of the chest, wheezing, drop in blood pressure, anxiety, nausea, vomiting, sweating, increased heart rate, , 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. 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.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Rarely	allergic type of reactions		X	X
	fever		X	X
	headache	X		

Very rarely	thromboembolic complications		X	X

This is not a complete list of side effects. For any unexpected effects while taking octaplex®, contact your doctor or pharmacist.

HOW TO STORE IT

Store protected from light at +2°C to +25°C. Do not freeze. After reconstitution as recommended (see *Instructions for reconstitution*), octaplex® should be administered immediately. However, if it is not administered immediately, the reconstituted solution can be stored for up to 8 hours at +2°C to +25°C, provided sterility of the stored product is maintained. Any solution remaining should be discarded.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
http://www.octapharma.ca
or by contacting Octapharma Canada Inc.,
at: 1-888-438-0488

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