

## PART III: CONSUMER INFORMATION

### OCTAPLASMA

[Solvent detergent (S/D) treated human plasma]

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

#### ABOUT THIS MEDICATION

##### What the medication is used for:

- Complex disorders of the blood clotting system due to severe liver failure, massive transfusion (this is the process of transferring blood or blood-based products from one person into the circulatory system of another), or repeated large volume plasma exchange. This is a removal procedure of (components of) blood plasma from the circulation (especially in patients with damaged liver function).
- OCTAPLASMA may be used for emergency therapy in clotting factor deficiencies, in special situations, e.g. when acute bleeding does not allow a precise laboratory diagnosis, or when a specific clotting factor concentrate is not available.
- Rapid conversion of the effects of oral anticoagulants (substances that prevent coagulation, i.e. they stop blood from clotting) when vitamin K is insufficient in emergency situations, or in patients with damaged liver function.

##### What it does:

The administration of OCTAPLASMA can temporarily stop bleeding in patients with clotting factor deficiencies in emergency situations, when vitamin K treatment is insufficient, or in patients with damaged liver function. OCTAPLASMA will start working immediately upon injection and the symptoms of bleeding should resolve.

##### When it should not be used:

- IgA deficiency, Severe deficiencies of protein S, plasma protein allergy, previous reaction to fresh frozen plasma or OCTAPLASMA, fluid in the lungs or cardiac failure.

##### What the medicinal ingredient is:

Human plasma proteins

##### What the important nonmedicinal ingredients are:

Glycine, Octoxynol, Sodium citrate dehydrate, Sodium dihydrogenphosphate dihydrate, TNBP

##### What dosage forms it comes in:

OCTAPLASMA (Solvent Detergent (S/D) Treated Human Plasma) is supplied frozen in bags of 200 mL containing 45-70 mg/mL Human Plasma Proteins.

Each 200 mL of OCTAPLASMA (Solvent Detergent (S/D) Treated Human Plasma) contains: Human plasma proteins (9.0-14.0 g), Sodium citrate dihydrate (0.88-1.48 g), Sodium

dihydrogenphosphate dihydrate (0.06-0.24 g), Glycine (0.80-1.20 g), TNBP (< 2.0 mcg/mL), Octoxynol (< 5.0 mcg/mL).

#### WARNINGS AND PRECAUTIONS

##### **Serious Warnings and Precautions**

This product is made from human plasma, which may contain infectious agents, such as viruses that cause hepatitis and other viral diseases. However, Octaplasma is treated to either remove or inactivate certain viruses. Pathogen inactivation of lipid enveloped viruses such as HIV, HBV and HCV is achieved through solvent detergent (S/D) treatment of plasma and the production process also allows immune neutralization of non-lipid enveloped viruses such as HAV and Parvovirus B19. Your doctor should discuss the risks and benefits of this product with you before giving you this product.

BEFORE you use OCTAPLASMA 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.
- If you are pregnant or nursing. A pregnancy test is recommended before receiving OCTAPLASMA.
- You are allergic to the active substance or to any of the ingredients.
- You have a disease that causes marked fibrinolysis that is responsible for breaking down blood clots.

#### INTERACTIONS WITH THIS MEDICATION

There is no known drug interaction to OCTAPLASMA. OCTAPLASMA administration may slow the protection of live attenuated vaccines such as measles, mumps, rubella (also known as three-day or liberty measles) and chicken pox for at least six weeks, and possibly up to three months or longer.

#### PROPER USE OF THIS MEDICATION

##### Usual dose:

The dose you receive will depend on your clinical situation and disease, but 12-15 mL OCTAPLASMA/kg body weight is a generally accepted starting dose. The duration of administration will be determined by your doctor.

##### Overdose:

Overdose may lead to volume overload and thereby water in the lung and/or heart failure. In such cases, OCTAPLASMA transfusion should be stopped immediately.

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:

Not applicable because OCTAPLASMA is usually given in a hospital setting.

Keep out of reach of children.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- Nausea, flushing, hives, fast heart rate, drop in blood pressure, reduction or cessation of breathing, and reduction or cessation of a sufficient amount of blood flow from the heart throughout the body that may result in impaired function of internal organs.
- In the course of plasma exchange, symptoms attributable to citrate overdose (e.g. fatigue, a sensation of tingling, numbness or prickling, tremor and low calcium concentrations) may occur.
- Acute lung injury, a syndrome known as transfusion related acute lung injury, may occur and is characterized by chills, fever, a non-productive cough, and difficulty or shortness of breath.
- Passive post-transfusion purpura (PTP) may occur which is characterized by difficulty or shortness of breath, rash, fever, discoloration of the skin that may include a reddish purple to brown color, and marked reduction in platelets.

## 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	
Rare	allergic type of reaction		T	T
	fever and/or chills	T		T
Very Rare	Shock		T	T
	abnormal heart rate		T	T
	fall or raise in blood pressure		T	T
	breathing disorders		T	T
	vomiting		T	T
	nausea	T		T
	skin reaction		T	T

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

## HOW TO STORE IT

Store frozen at < -18 °C, protect from exposure to light. After thawing OCTAPLASMA can be stored for up to 24 hours at +2-8 °C or for up to 8 hours at room temperature (+20 – 25 °C) before use. Thawed OCTAPLASMA must not be refrozen. Unused product must 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](http://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](http://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 the sponsor, Octapharma Canada Inc.  
at: 1-888-438-0488

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