



octaplex® 500IU/20ML

HUMAN PROTHROMBIN COMPLEX



Octaplex® is a lyophilized prothrombin complex concentrate (PCC) containing therapeutic and balanced levels of vitamin K-dependent coagulation factors (Factor II, VII, IX and X) and inhibitory protein C and S.

Active ingredients	Quantity per 20ml vial (IU)
Human coagulation factor II	280-760
Human coagulation factor VII	180-480
Human coagulation factor IX	500
Human coagulation factor X	360-600
Protein C	260-620
Protein S	240-640

Total protein: 260-820mg per vial

Excipients: Tri-sodium citrate dihydrate (75-125mg per vial), heparin (100-250 IU per vial)

INDICATION

Treatment of bleeding and perioperative prophylaxis of bleeding in:

01

Acquired deficiency of the prothrombin complex coagulation factors

(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)

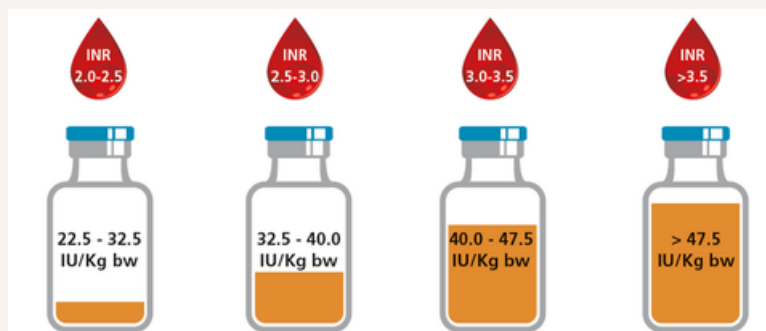
02

Congenital deficiency of factors II and X when purified specific coagulation factor products are not available.

DOSAGE

Bleeding/perioperative prophylaxis of bleeding during vitamin K antagonist therapy:

IV: Approximate doses required for normalization of INR (≤ 1.2 within 1 hour); dosage is expressed in units of factor IX activity:



Initial INR	2 - 2.5	2.5 - 3	3 - 3.5	> 3.5
Appropriate dose (IU Octaplex/kg body weight)	22.5-32.5	32.5-40.0	40.0-47.5	>47.5
Approximate dose (mL Octaplex/kg body weight)	0.9 - 1.3	1.3 - 1.6	1.6 - 1.9	> 1.9

For obese patient, use ideal body weight for dose calculation, the maximum single dose should not exceed 3000 IU (120mL Octaplex).

Contraindication

- Hypersensitivity to the active substance or to any of the excipients
- Known allergy to heparin or history of heparin induced thrombocytopenia.
- Individuals who have IgA deficiency with known antibodies against IgA.

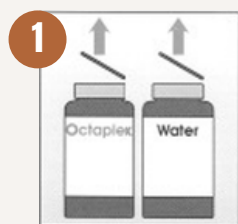
Administration

- Should be given as IV infusion
- IV line should be 'cleaned' by flushing it with NS or D5%
- Octaplex should not be mixed with any other product in the IV line
- Must be administered immediately after reconstitution.

Rate of infusion

The infusion should start at 1ml/min (60ml/H), followed by 2-3ml/min (120-180ml/H), using aseptic technique

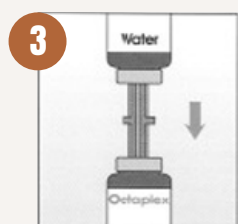
INSTRUCTION FOR RECONSTITUTION



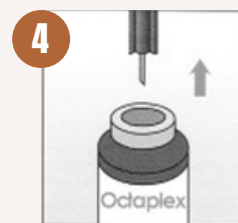
Warm the solvent (Water for Injections) and the powder (Octaplex) in the closed vials up to room temperature (not exceeding 37°C). Remove the caps from the powder vial and the water vial and clean the rubber stoppers with an alcohol swab.



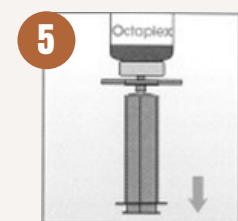
Remove the protective cover from the short end of the double-ended needle. Then perforate the centre of the water vial rubber stopper with the vertically held needle.



Remove the protective cover from the other, long end of the double-ended needle, making sure not to touch the exposed tip of the needle. Hold the water vial upside-down above the upright concentrate vial and quickly perforate the centre of the concentrate vial rubber stopper with the needle. The vacuum inside the concentrate vial draws in the water.



Remove the double-ended needle with the empty water vial from the concentrate vial, then slowly rotate the concentrate vial until the concentrate is completely dissolved. Octaplex dissolves quickly at room temperature to a colourless to slightly blue solution.



Remove the cap of the filter needle and attach a 20 mL syringe. Turn the vial with the attached syringe upside-down and draw up the solution into the syringe.

PRECAUTION

1. In patients with **acquired deficiency** of the vitamin K dependent coagulation factors, Octaplex should **only** be used **when rapid correction** of prothrombin complex levels is **necessary**, such as major bleeding or emergency surgery.
2. If **allergic or anaphylactic-type reactions** occur, the injection/infusion should be **stopped immediately**. In case of **shock**, standard medical treatment for shock should be implemented.

MONITORING

01 THROMBOEMBOLIC COMPLICATIONS

- Possible risk of **thrombosis or disseminated intravascular coagulations** with human prothrombin complex, particularly repeated dosing.
- **Close monitoring** should be exercised during administration in patients with:
 - History of coronary heart disease
 - Liver disease
 - Peri- or postoperative patients
 - Neonates
 - Risk of thromboembolic events or disseminated intravascular coagulation.
- **Potential benefit** of treatment should be **weighed against the risk** of these complications in each situation.

02 INCREASED PULSE RATE

- Patient's pulse rate should be measured **before and during the infusion**.
- If a **marked increase in the pulse rate** occurs, the infusion should be **slowed down** or the administration must be **interrupted**.

POLICY IN HUKM

- Octaplex is a NF drug.
- Patient can **pay at main lobby** (during office hour) or **emergency department** (after office hour) and show the **receipt inpatient pharmacy** (during office hour) or **emergency department pharmacy** (after office hour) to obtain the medication.
- Price: RM 714.15 per vial

Octaplex is ready to be used in life-threatening bleeding, unlike FFP:

OCTAPLEX	VS	FFP
20 - 40 mL	Volume	2100 mL (30 mL/kg)
10 mins	Onset of action	14 to 50 Hours
NOT required	Blood identification	Required
2°C - 25°C	Storage temperature	-25°C (Thawing time: 30 mins)



References:

1. Product Leaflet of Octaplex 2020. <https://www.medicines.org.uk/emc/files/pil.6566.pdf>
2. Octaplex Product Brochure 2018

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