octaplex® is effective in bleeding control

Mean INR before and after octaplex®

Only 1 dose of octaplex® to reverse INR

A single dose of octaplex® effectively controls bleeding. In 95% of the cases, a single dose of octaplex® was required to reverse INR. The percentage reached 100% in patients on warfarin and high risk of haemorrhage.

Accurate prevention and fast control of life-threatening bleeding

- Haemostatic balance of prothrombin complex coagulation factors
- Therapeutic concentrations of protein C and protein S
- Rapid INR reversal within 10 minutes
- Low thrombogenic profile
- Small volume and short infusion time

Intravenous administration

• 5 - 10 ml (250 - 500 unit)
• Each ml contains 250 - 500 units of prothrombin complex coagulation factors II (280 - 760 IU), VII (180 - 480 IU), IX (500 IU) and X (360 - 600 IU), Protein C (260 - 620 IU), Protein S (240 - 640 IU) and total protein (260 - 820 mg).

Indications:
- The need for rapid correction of coagulation factors II, VII, IX and X, Protein C and Protein S in patients with bleeding episodes or situations at risk of bleeding.
- Rapid correction of coagulation disorders due to massive bleeding.
- Treatment of life-threatening bleeding as a result of haemorrhagic complications due to heparin therapy.
- Treatment of life-threatening bleeding as a result of heparin-induced thrombocytopenia.
- Haemorrhagic disorders associated with congenital deficiencies of the vitamin K dependent coagulation factors II and X when purified factor activities decrease to such an extent that they manifest as poor clinical response.
- Treatment of major bleeding complications in patients undergoing cardiac surgery, orthopaedic surgery and trauma.
- In patients with a history of coronary heart disease or liver disease, at risk of thrombosis or DIC, neonates, and peri- or post-operative patients.

Contraindications:
- Hypersensitivity to active substance, excipients or heparin.
- History of heparin-induced thrombocytopenia.
- Pregnancy, during breast-feeding.

Cautions:
- Accurate prevention and fast control
- Accurate prevention and fast control

Dosage and duration of substitution therapy depends on the severity of the coagulation disorder, location and extent of the coagulation defect and on the contribution of other coagulation factors.

OAT Liver

• Recommended dose in patients with liver dysfunction.


Rossaint R et al. The European guideline on management of major bleeding and coagulopathy following trauma. Critical Care 2016; 20:100


OAT Liver

• Small volume and short infusion time

1. Summary of Product Characteristics of octaplex®

2. Information on side effects, contraindications and precautions

3. How to use for high risk of haemorrhage

4. Quick facts

5. Advantages over other products

6. Only 1 dose of octaplex® to reverse INR

7. Accurate prevention and fast control

8. Effective in bleeding control

9. Accurate prevention and fast control

10. Accurate prevention and fast control

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30. Accurate prevention and fast control
Octaplex® is the 4 factor PCC with balanced composition

Octaplex® is a lyophilised prothrombin complex concentrate (PCC) containing therapeutic and balanced levels of vitamin K-dependent coagulation factors (II, VII, IX and X) and inhibitory proteins C, S and F. It replaces pro-coagulant factors and inhibitory proteins in a fast and balanced way. Octaplex® is indicated for:

- Minimising delay in initiating treatment is of crucial importance not only in serious bleeding like intracranial haemorrhage (ICH), but also in emergency surgery or invasive procedure.
- Octaplex® reduces the time to achieve INR reversal due to:
  - Ion exchange chromatography for further reduction of non-enveloped viruses
  - Solvent detergent (SD) treatment to inactivate possible enveloped viruses
  - Filtration to remove viruses

Current international guidelines on bleeding management recommend the use of octaplex® to prevent and control life-threatening bleeding.

Minimising delay in initiating treatment is of crucial importance not only in serious bleeding like intracranial haemorrhage (ICH), but also in emergency surgery or invasive procedure.

Octaplex® is well tolerated and shows low thrombogenicity.

Due to the lower incidence of adverse events when compared to FFP, octaplex® should be considered a first-line treatment for OAT reversal.

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

Compared with FFP, octaplex® as a 4-factor PCC provides quicker and more controlled correction of INR, improving bleeding control.

Clinical trials with octaplex® or FFP (%)

<table>
<thead>
<tr>
<th>Initial INR</th>
<th>Octaplex®</th>
<th>FFP</th>
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<tbody>
<tr>
<td>2.0 - 2.5</td>
<td>40.0%</td>
<td>2.7%</td>
</tr>
<tr>
<td>2.5 - 3.5</td>
<td>11.6%</td>
<td>2.0%</td>
</tr>
<tr>
<td>3.5 - 4.5</td>
<td>3.5%</td>
<td>2.0%</td>
</tr>
<tr>
<td>4.5 - 5.5</td>
<td>0%</td>
<td>2.0%</td>
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The use of octaplex® is recommended

Current guidelines recommend the use of a 4-factor PCC for urgent VKA reversal:

- The British Committee for Standards in Haematology
- The American College of Chest Physicians
- The French clinical practice guidelines
- The Board of the German Medical Association
- The European guidelines on the management of postoperative bleeding
- The American Association of Blood Banks

These recommendations reflect findings from a range of studies showing that PCCs are effective in lowering INR for prompt VKA reversal.

Individualised dosage of octaplex®

The amount and frequency of administration should be calculated on an individual patient basis. The dose will depend on baseline INR and the defined target value.

Approximate doses required for normalisation of INR (± 1.5 within 1 hour) at different initial INR levels.

Intraoperative dose

<table>
<thead>
<tr>
<th>Initial INR</th>
<th>Octaplex® dose</th>
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<tbody>
<tr>
<td>5 - 10</td>
<td>1500 IU/Kg bw</td>
</tr>
<tr>
<td>10 - 15</td>
<td>2000 IU/Kg bw</td>
</tr>
<tr>
<td>15 - 20</td>
<td>2500 IU/Kg bw</td>
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In a retrospective study, only 4 out of 668 patients treated with octaplex® to reverse OAT showed an incidence of thrombotic events, confirming the low thrombogenic risk.