# RULES FOR INTERCHANGEABLE BLOOD PRODUCTS

**REASON FOR ISSUE: Update to include Beriplex NZ and separate PCC from Factor IX section. Removed reference to Intragam-P.**

| Pharmacopoeia Title | Product Prescribed | Product Description | Current Position | Substitution (See Definitions at end of table) | Informed Consent in event of Substitution |
|---|---|---|---|---|---|
| Albumin | Alburex 5 NZ | Alburex 5 NZ (5% 500mL) solution for infusion | Available | No substitution | Not Applicable |
| | Alburex 20 NZ | Alburex 20 NZ (20%) solution for infusion | Available | Albumex 20 | None Required |
| | Albumex 4 | Albumex 4 (4%) solution for infusion | Available | No substitution | Not Applicable |
| | Albumex 20 | Albumex 20 (20%) solution for infusion | Available | Alburex 20 NZ | None Required |
| Alpha$_1$-Proteinase Inhibitor | Zemaira | Alpha$_1$-proteinase inhibitor (A$_1$-PI) concentrate | Section 29 Product | No substitution | Not Applicable |
| Antithrombin III | Kybernin P | Antithrombin III Concentrate | Section 29 Product | No substitution | Not Applicable |
| C1-Esterase Inhibitor | C1-Esterase Inhibitor | C1 Esterase Inhibitor, Human | Generally available. Section 29 Product | Substitute Berinert C1 Esterase Inhibitor, Human | None Required |
| | Berinert or Berinert P | Berinert C1 Esterase Inhibitor, Human | Section 29 Product | No substitution | Not Applicable |
| | Berinert SC | Berinert SC C1 Esterase Inhibitor, Human | Section 29 Product | No substitution | Not Applicable |
| Factor VIIa | NovoSeven RT | Recombinant Coagulation Factor VIIa (rFVIIa) | Available | No substitution | Not Applicable |
| Factor VIII<br><br>Antihaemophilic Factor (human) | Biostate | Biostate Injection with diluent, FVIII/VWF complex | Available | No substitution | Prescription for Factor VIII must identify a specific product.<br><br>Generic Prescriptions are not acceptable |
| | Advate | Antihaemophilic Factor (Recombinant) Short half-life | Available | No substitution | |
| | Koate-DVI | Antihaemophilic Factor (Recombinant) | Section 29 Product | No substitution | |
| | Adynovate | Antihaemophilic Factor (Recombinant) Extended half-life | Available | No substitution | |

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|---|---|---|---|---|---|
| Factor IX | RIXUBIS | Coagulation Factor IX (Recombinant)<br>Short half-life | Available | No substitution | Prescription for Factor IX must identify a specific product.<br><br>Generic prescriptions not acceptable |
| | Alprolix | Coagulation Factor IX (Recombinant)<br>Extended half-life | Available | No substitution | |
| Prothrombin Complex Concentrates | Prothrombinex-VF | Prothrombinex-VF<br>Human Prothrombin complex concentrate, powder for injection (Factors II, IX, X) | Available | No substitution | Prescription for PCC must identify specific product.<br><br>Generic prescription not acceptable<br>? |
| | Beriplex NZ | Beriplex NZ<br>Human Prothrombin complex concentrate, powder for injection (Factors II, VII, IX, X) | Available | No substitution | |
| Factor XIII | Fibrogammin | Fibrogammin (FXIII) | Available | No substitution | Not Applicable |
| Factor VIII inhibitor bypassing fraction | FEIBA NF | Activated Prothrombin Complex against FVIII Antibodies | Available | No substitution | Not Applicable |
| Fibrinogen Concentrate (Coagulation Factor 1) | RiaSTAP | Lyophilised plasma derived human fibrinogen | Available | No substitution | Not Applicable |
| Hepatitis B Immunoglobulin, solution for intramuscular injection | Hepatitis B Immunoglobulin-VF | Hepatitis B Immunoglobulin - VF | Available | No substitution | Not Applicable |
| | HyperHEP B | Hepatitis B Immune Globulin (Human) | Available, 110 IU dose only | No substitution | Not Applicable |
| Human Normal Immunoglobulin, solution for intramuscular injection | Normal Immunoglobulin | Normal Immunoglobulin - VF | Generally available | No substitution | Not Applicable |

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| Human Anti-D (Rho) Immunoglobulin | Anti-D Immunoglobulin | Rh(D) Immunoglobulin-VF or Rhophylac | Available | Rh(D) Immunoglobulin-VF, & Rhophylac are forms of Anti-D Immunoglobulin.<br>No substitution is involved but inform prescriber if a Section 29 product is provided. | Not Applicable |
| | Rh(D) Immunoglobulin-VF | Rh(D) Immunoglobulin-VF | Generally available | Substitute Rhophylac. Inform prescriber that it is a Section 29 medicine | Patient must be informed where a substitution has been made |
| | Rhophylac | Rhophylac (intravenous or intramuscular solution) | Available, 1500 IU dose Section 29 Product | No substitution | Not Applicable |
| Human Normal Immunoglobulin, solution for intravenous injection | Privigen NZ | Privigen NZ (10% (100g/L)) solution for intravenous infusion. | Access restricted requires TMS approval. | Not permitted.<br>Product supplied must match patient approval (IgO/eTraceline)<br>*Refer Table 2 if product request does not match product supplied.* | Patients must be informed where a change to the approved product is required. |
| | Privigen | Privigen (10% (100g/L)) solution for intravenous infusion. | Access restricted requires TMS approval. | Not permitted.<br>Product supplied must match patient approval (IgO/eTraceline)<br>*Refer Table 2 if product request does not match product supplied.* | Patients must be informed where a change to the approved product is required. |
| | Gamunex 10% | Normal Immunoglobulin (Human), 10%, 100 mg/mL, Solution for Intravenous or Subcutaneous Administration | Access restricted requires TMS approval | No substitution | Not Applicable |
| Human Immune Globulin for subcutaneous administration | Hizentra NZ | Hizentra NZ (20% (20 g/100 mL)), solution for subcutaneous injection. | Access restricted requires TMS approval. | Not permitted.<br>Product supplied must match patient approval (IgO/eTraceline)<br>*Refer Table 2 if product request does not match product supplied.* | Patients must be informed where a change to the approved product is required. |

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|---|---|---|---|---|---|
| | Hizentra | Hizentra (20% (20 g/100 mL)), solution for subcutaneous injection. | Access restricted requires NZBS TMS MO approval. | Not permitted.<br>Product supplied must match patient approval.<br>*Refer Table 2 if product request does not match product supplied.* | Patients must be informed where a change to the approved product is required. |
| Human Rabies Immunoglobulin | Berirab P | Human rabies immunoglobulin | Section 29 medicine | No substitution | Not Applicable |
| Human Tetanus Immunoglobulin | Tetanus Immunoglobulin-VF | Tetanus Immunoglobulin-VF 250 IU, solution for intramuscular injection | Generally available | Either product can be issued/dispensed. Inform prescriber that it is a Section 29 medicine | Patient must be informed when a substitution has been made |
| | Tetagam P | Human Tetanus Immunoglobulin | Section 29 Product | | |
| Idarucizumab | Praxbind | Praxbind solution for Injection/Infusion | Available | No substitution | Not Applicable |
| Zoster Immunoglobulin | Zoster Ig-VF | Human Zoster Immunoglobulin | Generally available | No substitution | Not Applicable |

**Substitution – Definitions:**

'No substitution': There is no alternative product available with the same active ingredient, dose and strength.

'Not permitted': There is an alternative product available however substitution is not permitted because of an additional reason/s eg: the plasma source differs significantly between products.

**Table 2: Immunoglobulin Substitutions**

Privigen® NZ and Privigen® are different products, likewise Hizentra® NZ and Hizentra® are different products. While these products technically fit the requirements for interchangeable medicines, only the version of the product approved as recorded in IgO or eTraceline for the patient should be issued/dispensed. A mixture of different products (e.g. Privigen® and Privigen® NZ) should not be issued at one time, or if to be administered over 2-5 days, the same product should be issued for the whole occurrence.

| Requested Product | Scenario | Subsequent Action |
|---|---|---|
| Requested product does not match approved product in eTraceline / IgO and prescribing clinician has been contacted. e.g. Hizentra® instead of Hizentra® NZ | Error in product trade name recorded on request form or prescription | Confirm with clinician that approved product will be supplied. Amend prescription/issue form to approved product, sign, and date. Record that Prescribing Clinician has been notified. Supply the approved product. |
| | Prescribing Clinician requests the alternative version to the approved product | Product issued must match approved product. Contact TMS to update the approval. Prescribing clinician should be notified that informed consent will be required. Once approval updated, supply approved product. |
| Requested product matches approved product in eTraceline / IgO | Approved product not available in inventory within an acceptable timeframe | Contact TMS for approval of a one-off substitution. Prescribing clinician should be notified of substitution and that informed consent will be required. Once approval updated, supply approved product. |
| Pharmacopoeia Title e.g IVIg, SCIg, Intravenous Immunoglobulin, Subcutaneous Immunoglobulin | Error in prescription or request form | Request must be for the product trade name. Contact Prescribing Clinician and request that a new prescription or request form is supplied for the approved product. |