INFORMATION ONLY

Tretten® Distribution

Customer Letter # 2013-06

2013-02-12

Dear Customer:

Novo Nordisk received Health Canada licensure for their recombinant coagulation FXIII-A subunit under the name Tretten® and the product is available for distribution through Canadian Blood Services. Please refer to the enclosed Dear Health Care Professional Letter and Dose Reference Card from Novo Nordisk for further details.

Tretten® is indicated for routine prophylaxis for bleeding in patients with congenital factor XIII A-subunit deficiency. Tretten® should not be used for prophylactic treatment of bleeding in patients with congenital factor XIII B-subunit deficiency.

Canadian Blood Services currently distributes Fibrogammin P, an unlicensed plasma derived FXIII manufactured by CSL Behring, through Health Canada’s Special Access Programme. Please see table below for indications of Fibrogammin P.

CSL Behring will continue to make Fibrogammin P available for patients. Physicians may continue requesting approval for Fibrogammin P on a case by case basis through the Health Canada Special Access Programme as appropriate.

<table>
<thead>
<tr>
<th>Product</th>
<th>Tretten®</th>
<th>Fibrogammin P</th>
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<tbody>
<tr>
<td>Indication</td>
<td>• Routine prophylaxis for bleeding in patients with congenital factor XIII A-subunit deficiency</td>
<td>• Congenital deficiency of Factor XIII and resulting haemorrhagic diathesis, haemorrhages and disturbances in wound healing</td>
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<td></td>
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<td>• Haemorrhagic diatheses caused completely or in part by acquired Factor XIII deficiency</td>
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<td>• Supportive therapy in case of disturbance in wound healing, especially in ulcus cruris, after large surgery or injuries</td>
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<tr>
<td>Vial Size</td>
<td>• 2500IU</td>
<td>• 250 IU</td>
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<td>• 1250 IU</td>
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Customers will see the assigned CBS Code for Tretten® (material master number 1000106413) on the Factor Concentrate, Unlicensed Plasma Products and S/D Plasma Order Form.

The revised Order Form can be downloaded from www.blood.ca by following the links to “Hospitals” and “Hospital Customer Forms”, which is password protected. Please contact your local Hospital Liaison Specialist to obtain the User Name and Password. Canadian Blood Services will notify hospitals when the revised Order Form is posted.
For further information regarding Tretten®, please contact Novo Nordisk Canada at 1800-465-4334.

This Customer Letter and any enclosures can also be viewed at [www.blood.ca](http://www.blood.ca) in the “Hospitals” section.

If you have questions about this Customer Letter, please contact Ellie Kingsbury at email address [elenore.kingsbury@blood.ca](mailto:elenore.kingsbury@blood.ca).

Sincerely,

Dana Devine, Ph.D.
Vice President, Medical, Scientific & Research Affairs