Table 1: Description of IXINITY, Coagulation Factor IX (Recombinant), is a human blood coagulation factor indicated in adults and children ≥12 years of age with hemophilia B for:

2. On-demand treatment and control of bleeding episodes
3. Perioperative management of bleeding

Table 2: Dose and Administration

<table>
<thead>
<tr>
<th>Dosage Form and Strengths</th>
<th>Nominally 250, 500, 1000, 1500, 2000, or 3000 IU per vial.</th>
</tr>
</thead>
</table>

Table 3: Summary of Adverse Reactions

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Number of Subjects (n = 77)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe or life-threatening</td>
<td>30</td>
</tr>
<tr>
<td>Moderate</td>
<td>131</td>
</tr>
</tbody>
</table>

Table 4: Description of Pharmacokinetics

<table>
<thead>
<tr>
<th>Pharmacokinetic Parameter</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tmax (hours)</td>
<td>1.5 (0.5)</td>
</tr>
<tr>
<td>T1/2 (hours)</td>
<td>2 (0.5)</td>
</tr>
</tbody>
</table>

Table 5: Description of Metabolism

<table>
<thead>
<tr>
<th>Metabolism</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clearance</td>
<td>3.5 (0.5)</td>
</tr>
<tr>
<td>Half-life</td>
<td>2 (0.5)</td>
</tr>
</tbody>
</table>

Table 6: Description of Excretion

<table>
<thead>
<tr>
<th>Excretion</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary</td>
<td>3.5 (0.5)</td>
</tr>
<tr>
<td>Biliary</td>
<td>2 (0.5)</td>
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</tbody>
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Table 7: Description of Contraindications

<table>
<thead>
<tr>
<th>Contraindication</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergy</td>
<td>3.5 (0.5)</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>2 (0.5)</td>
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</tbody>
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Table 8: Description of Dosage and Administration

<table>
<thead>
<tr>
<th>Dosage and Administration</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>On-demand treatment and control of bleeding episodes</td>
<td>3.5 (0.5)</td>
</tr>
<tr>
<td>Perioperative management of bleeding</td>
<td>2 (0.5)</td>
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Table 9: Description of Monitoring

<table>
<thead>
<tr>
<th>Monitoring Parameters</th>
<th>Mean (SD)</th>
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</thead>
<tbody>
<tr>
<td>Factor IX activity</td>
<td>3.5 (0.5)</td>
</tr>
<tr>
<td>Platelet count</td>
<td>2 (0.5)</td>
</tr>
</tbody>
</table>

9. SUMMARY OF OTHER IMPORTANT SAFETY INFORMATION

10. CLINICAL STUDIES

11. DESCRIPTION

12. CLINICAL PHARMACOLOGY

13. ADVERSE REACTIONS

14. DOSAGE AND ADMINISTRATION

15. DOSAGE FORMS AND STRENGTHS

16. DDI PHARMACOKINETICS

17. PATIENT CONSENTING INFORMATION AND FDA approved patient labeling.

18. INSTRUCTIONS FOR DILUTION

19. INSTRUCTIONS FOR USE

20. INSTRUCTIONS FOR DISPOSAL

21. INSTRUCTIONS FOR STORAGE AND HANDLING

22. INSTRUCTIONS FOR USE

23. INSTRUCTIONS FOR USE

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200. INSTRUCTIONS FOR USE
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