Iprivask® 15mg (for injection)

**SPOVIDINAL ENDOVASCULAR ANGIOPLASTY**

When vascular diseases (abdominal aortic aneurysm) are present, surgical treatment is recommended. Patients with severe arterial disease should be considered for endovascular treatment, including balloon angioplasty or stenting. These procedures can be performed with local or general anesthesia, depending on the complexity of the case.

**PEXICULAR DERANGEMENTS**

When desirudin is used for surgical treatment of abdominal aortic aneurysm, the surgeon should be aware of the potential for postoperative bleeding and should be prepared to manage any complications that may arise. The clinical presentation and treatment of these complications are beyond the scope of this document.

**DESCRIPTION**

Desirudin (also known as hirudin) is a naturally occurring anticoagulant derived from the blood of medicinal leeches. It is a single amino acid chain (150 residues) of the large subunit of the leech anticoagulant.

**Distribution:** Desirudin is rapidly distributed throughout the body, with a mean apparent volume of distribution of 0.75 liters per kilogram of body weight. The drug is secreted into the urine in its original form, with a small fraction excreted as metabolites. Desirudin is not metabolized in the liver and is not renally excreted.

**Pharmacokinetics:** Desirudin is a highly protein-bound drug, with a plasma half-life of approximately 2 to 3 hours. The drug is cleared primarily through glomerular filtration and tubular secretion. The elimination half-life is approximately 4 to 6 hours.

**CLINICAL PHARMACOLOGY**

Desirudin is a potent and selective inhibitor of thrombin and factor Xa. It is not affected by the presence of antithrombin III, and it is not neutralized by hirudin antibodies. Desirudin is a highly specific and potent anticoagulant.

**Contraindications**

Desirudin is contraindicated in patients with a history of hemorrhage, or with an increased risk of bleeding. It should also be used with caution in the presence of certain medical conditions, such as renal impairment, hepatic impairment, and pregnancy.

**Warnings**

The use of desirudin is associated with a risk of hemorrhage, particularly in patients with a history of bleeding disorders or increased risk of bleeding. Patients should be monitored closely for signs of bleeding.

**DOSAGE AND ADMINISTRATION**

Desirudin is administered subcutaneously, usually at a dose of 15 mg every 12 hours. The dose may be adjusted based on the patient's response and laboratory values.

**PREGNANCY**

Desirudin is not recommended for the treatment of pregnant women due to the potential risk of fetal harm. However, the use of desirudin in pregnant women should be considered in patients with life-threatening coagulopathy who are refractory to alternative treatments.

**LACTATION**

The safety of desirudin in breastfeeding mothers has not been established. However, desirudin is not expected to be excreted in human milk.

**ADVERSE REACTIONS**

The most common adverse reactions associated with desirudin treatment are gastrointestinal reactions, including nausea, vomiting, and diarrhea. Other adverse reactions include headache, dizziness, and fatigue.

**PRECAUTIONS**

Desirudin should be used with caution in patients with a history of bleeding disorders or increased risk of bleeding. It should be used with caution in patients with renal or hepatic impairment.

**INTERACTIONS**

Desirudin is not known to interact with other anticoagulants, antiplatelet agents, or nonsteroidal anti-inflammatory drugs (NSAIDs).

**FOR INFORMATION**

For more information, please refer to the package insert or consult with a healthcare provider.
**Hemorrhage in Patients Undergoing Hip Replacement Surgery**

**Dosing Regimes**

<table>
<thead>
<tr>
<th>Dosing Regimen</th>
<th>Iprivask</th>
<th>Heparin</th>
<th>Enoxaparin</th>
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<tbody>
<tr>
<td>15 mg (QD) SC</td>
<td>100 IU (QD) SC</td>
<td>40 mg (QD) SC</td>
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<tr>
<td>25 mg (QD) SC</td>
<td>150 IU (QD) SC</td>
<td>60 mg (QD) SC</td>
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<tr>
<td>50 mg (QD) SC</td>
<td>250 IU (QD) SC</td>
<td>120 mg (QD) SC</td>
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**Patients with Any Hemorrhage**

<table>
<thead>
<tr>
<th>n (%)</th>
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<tbody>
<tr>
<td>501 (20)</td>
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**Patients with Severe Hemorrhage**

<table>
<thead>
<tr>
<th>n (%)</th>
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<tbody>
<tr>
<td>201 (8)</td>
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**Patients with Major Hemorrhage**

<table>
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<th>n (%)</th>
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<tr>
<td>46 (2)</td>
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**Non-hemorrhagic Events:**

- **Related Events with a Frequency of ≥2% and >0.2%**
  - Thrombosis, intracranial, intraocular, extraspinal, or occurred in a major prosthetic joint.
  - Wound Secretion
  - Injection Site Mass

- **Non-hemorrhagic Events occurring at a ≥2% Incidence in patients treated with Iprivask:**
  - Nausea

- **Non-hemorrhagic Events occurring at a ≥2% Incidence in patients treated with Iprivask:**
  - Nausea

- **Related Adverse Events with a Frequency of <2% and >0.2%**
  - Bleeding complications were considered

- **In case of overdose, most likely reflected in hemorrhagic complications or suggested by excessively high aPTT values**

**Post Marketing:**

- In addition to adverse events reported from clinical trials, the following adverse events have been identified during post approval use of Iprivask. These events were reported voluntarily from a population of 1036 patients (as of March 2014).

**Adverse Events Occurring at a ≥2% Incidence in Patients Undergoing Hip Replacement Surgery**

<table>
<thead>
<tr>
<th>Body System</th>
<th>Preferred Term</th>
<th>n (%)</th>
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<tbody>
<tr>
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<td>-</td>
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</table>

**WARNINGS:**

- Use Iprivask before the expiration date given on the carton and container.
- Only use enclosed Eclipse™ needle. Attach Needle to Syringe by twisting. Pull pink lever down and pierce rubber stopper and snaps into place. Discard Vial Adapter package.

**Contraindications:**

- Use Iprivask before the expiration date given on the carton and container.
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