The recommended dose of enoxaparin sodium is 40 mg once a day. Administration is 7 to 10 days after surgery.

**WARNING:** SPINAL/EPIDURAL HEMATOMAS

Patients undergoing spinal or epidural anesthesia or lumbar puncture may be predisposed to bleeding complications. Enoxaparin sodium may affect the hemostatic balance and may contribute to the occurrence of spinal hematoma, possibly leading to paraplegia or other serious complications.

Other drugs that affect hemostasis, such as non-steroidal anti-inflammatory drugs (NSAIDs), aspirin and other salicylates, warfarin sodium, direct thrombin inhibitors (e.g., argatroban, lepirudin, hirudin), and bivalirudin, increase the risk of bleeding complications with enoxaparin sodium.

**INDICATIONS AND USAGE**

- **Ischemic Complications of Unstable Angina and Non–Q-Wave Myocardial Infarction**
- **Prevention of Deep Vein Thrombosis (DVT),** Prevention of Pulmonary Embolism (PE) in Patients Undergoing Hip, Knee, or Abdominal Surgery
- **Treatment of Deep Vein Thrombosis (DVT) and Prevention of Pulmonary Embolism (PE)** in Patients Undergoing Hip, Knee, or Abdominal Surgery
- **Prophylaxis and Treatment of Thromboembolic Disease in the Obese Patient**
- **Prevention of Thromboembolic Disease in Obese Patients Undergoing General or Obstetric Surgery**
- **Prevention of Deep Vein Thrombosis** in Patients Undergoing Total Joint Replacement

**CONTRAINDICATIONS**

- Hypersensitivity to enoxaparin sodium or any other component of this product

**WARNINGS**

- **Spinal Hematoma:**预警：脊髓/硬膜外血肿
- **Heparin-induced Thrombocytopenia (HIT):** Use of enoxaparin sodium in patients with a history of immune-mediated HIT within the past 100 days or in the presence of HIT antibodies, irreversible platelet aggregation, or thrombosis is contraindicated.

**PRECAUTIONS**

- **Monitoring of Hemostasis:** Regular monitoring of hemostasis is recommended, especially in patients undergoing surgery, who may be at higher risk for bleeding complications.

**ADVERSE REACTIONS**

- **Adverse Reactions Occurring at ≥2% Incidence in Enoxaparin Sodium–Treated Patients Undergoing Treatment of Acute ST-Segment Elevation Myocardial Infarction**

**DRUG INTERACTIONS**

- **Intravenous bolus**
- **Subcutaneous dose followed by 1 mg/kg**

**DOSE FORMS AND STRENGTHS**

- Enoxaparin sodium injection is available in two concentrations.

**PREGNANCY**

- Use of enoxaparin sodium in pregnant women is not recommended. Approximately 1.7% of women used enoxaparin during pregnancy. A total of 341 pregnancies resulted in 346 live births. There were 10 cases of neonatal hemorrhage.

**NURSING MOTHERS**

- Enoxaparin sodium may be administered if enoxaparin sodium was administered greater than 8 hours previous to the protamine sulfate bolus. Enoxaparin sodium should not be administered to women who are breastfeeding.

**REPRODUCTION**

- Enoxaparin sodium injection contains benzyl alcohol, which may cause toxicity in infants.

**PATIENT COUNSELING INFORMATION**

- Patients should be instructed to report immediately if they experience any of the above signs or symptoms. If signs or symptoms of spinal hematoma are suspected, the physician must be notified immediately.

**HOW SUPPLIED**

- Enoxaparin sodium injection, for subcutaneous and intravenous use

**FULL PRESCRIBING INFORMATION**

- See detailed prescribing information including BOXED WARNING, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, DRUG INTERACTIONS, DOSAGE FORMS AND STRENGTHS, PREGNANCY, NURSING MOTHERS, REPRODUCTION, PATIENT COUNSELING INFORMATION, HOW SUPPLIED.
The volume of distribution of anti-Factor Xa activity is about 4.3 L. Slightly higher in males than in females. The source of the gender difference in these parameters has not been conclusively determined.

Enoxaparin sodium injection

Renal impairment

A 30 mg intravenous bolus immediately followed by a 1 mg/kg subcutaneous administration resulted in aPTT postinjection values.

Enoxaparin sodium is obtained by alkaline depolymerization of heparin benzyl ester derived from porcine intestinal mucosa.

*5000 U q8h subcutaneously

Table 17: Efficacy of Enoxaparin Sodium in the Prophylaxis of Deep Vein Thrombosis Following Hip Replacement Surgery

<table>
<thead>
<tr>
<th>Indication</th>
<th>Enoxaparin Sodium</th>
<th>Placebo</th>
<th>Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal DVT (%)</td>
<td>17 (11)</td>
<td>8 (4)†</td>
<td>0.09</td>
</tr>
<tr>
<td>Complications</td>
<td>1223 (12.0)</td>
<td>1529 (100)</td>
<td>0.08</td>
</tr>
</tbody>
</table>

* p value versus placebo = 0.0002

Restricted Mobility during Acute Illness

In a single study, elimination rate appeared similar but AUC was two-fold higher than control population, after a single 0.25 or 0.5 mg/kg IV bolus, and 1.0 mg/kg IV bolus, respectively.

Table 19: Efficacy of Enoxaparin Sodium in the Extended Prophylaxis of Deep Vein Thrombosis Following Hip Replacement

<table>
<thead>
<tr>
<th>Indication</th>
<th>Enoxaparin Sodium</th>
<th>Placebo</th>
<th>Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal DVT (%)</td>
<td>5 (6)‡</td>
<td>4 (5.1)</td>
<td>0.08</td>
</tr>
<tr>
<td>Complications</td>
<td>531 (5.2)</td>
<td>383 (3.7)</td>
<td>0.09</td>
</tr>
</tbody>
</table>

* All patients were also treated with aspirin 100 to 325 mg per day.

14.4 Treatment of Deep Vein Thrombosis with or without Pulmonary Embolism

*The primary efficacy endpoint was the composite of death from any cause or myocardial re-infarction in the first 30 days. The incidence of DVT during extended prophylaxis was significantly lower for enoxaparin sodium compared to placebo, with a 95% CI of 8.8 to 15.7.

Table 25: Efficacy of Enoxaparin Sodium in the Treatment of Acute ST-Segment Elevation Myocardial Infarction

<table>
<thead>
<tr>
<th>Indication</th>
<th>Enoxaparin Sodium</th>
<th>Placebo</th>
<th>Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal DVT (%)</td>
<td>383 (3.7)</td>
<td>1223 (12.0)</td>
<td>0.08</td>
</tr>
<tr>
<td>Complications</td>
<td>156 (1.5)</td>
<td>1529 (100)</td>
<td>0.09</td>
</tr>
</tbody>
</table>

*All patients were also treated with warfarin sodium commencing on the evening of the second day of enoxaparin sodium or standard heparin therapy.