5.5 Thrombocytopenia  

2.7 Converting to Warfarin

Adjust the dosage of Heparin Sodium Injection according to the patient's coagulation test results. Dosage is considered because of the risk of hematoma at the injection site.

"catheter lock flush" syringe or other 1 mL syringe of incorrect strength

These highlights do not include all the information needed to use HEPARIN SODIUM INJECTION safely and effectively.

HIGHLIGHTS OF PRESCRIBING INFORMATION

• Prophylaxis and treatment of venous thrombosis and pulmonary embolism

Intravenous

Use a different site

15,000 units to 20,000 units of a concentrated solution

Subcutaneously

to 20,000 units of a concentrated solution

The dosing recommendations in Table 1 are based on clinical experience. Although dosages must be adjusted for the individual

less than 60 minutes, or 400 units per kilogram for those estimated to last longer than 60 minutes.

Most common adverse reactions are hemorrhage, thrombocytopenia, HIT and HITT, injection site irritation, general

see Adverse Reactions (6.1)

• Hemorrhage is the chief complication that may result from heparin therapy. Do not use the blue pack in the

• Local irritation, erythema, mild pain, hematoma or ulceration may follow deep subcutaneous

• Reactions following the subcutaneous administration of heparin sodium are most often localized to the injection site,

• Abrupt discontinuation after long-term heparin therapy is associated with a rebound hyperlipemia.

• Hypersensitivity

• Heparin Resistance

• Hemorrhage

• Other - Menstruation, liver disease with impaired hemostasis.

• Patients with hereditary antithrombin III deficiency receiving concurrent antithrombin III therapy

• Reactions following the subcutaneous administration of heparin sodium are very frequent and local. Most reactions

• Reactions following the subcutaneous administration of heparin sodium are most often localized to the injection site.

• Local irritation

• The dosing recommendations in Table 1 are based on clinical experience. Although dosages must be adjusted for the individual

• Hemorrhage is the chief sign of heparin overdosage.

• The dosing recommendations in Table 1 are based on clinical experience. Although dosages must be adjusted for the individual

• Local irritation

• Abrupt discontinuation after long-term heparin therapy is associated with a rebound hyperlipemia.

• Hemorrhage is the chief complication that may result from heparin therapy.

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• Reactions following the subcutaneous administration of heparin sodium are most often localized to the injection site.

• Local irritation
16 HOW SUPPLIED/STORAGE AND HANDLING

Heparin Sodium Injection, USP is a preservative-free clear solution available as:

**Product Code Unit of Sale Strength Each**

<table>
<thead>
<tr>
<th>NDC 63323-118-05</th>
<th>Unit of 24</th>
<th>5,000 USP units per 0.5 mL (10,000 USP units per mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDC 63323-118-01</td>
<td>0.5 mL fill in 1 mL prefilled single-dose syringe</td>
<td></td>
</tr>
</tbody>
</table>

Discard unused portion.

Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature].

Protect from freezing.

Do not place syringe on a sterile field.

17 PATIENT COUNSELING INFORMATION

**Hemorrhage**

Inform patients that it may take them longer than usual to stop bleeding, that they may bruise and/or bleed more easily when they are treated with heparin, and that they should report any unusual bleeding or bruising to their physician. Hemorrhage can occur at virtually any site in patients receiving heparin. Fatal hemorrhages have occurred [see Warnings and Precautions (5.2)].

**Prior to Surgery**

Advise patients to inform physicians and dentists that they are receiving heparin before any surgery is scheduled [see Warnings and Precautions (5.2)].

**Heparin-Induced Thrombocytopenia**

Inform patients of the risk of heparin-induced thrombocytopenia (HIT). HIT may progress to the development of venous and arterial thromboses, a condition known as heparin-induced thrombocytopenia and thrombosis (HITT). HIT and HITT can occur up to several weeks after the discontinuation of heparin therapy [see Warnings and Precautions (5.3)].

**Hypersensitivity**

Inform patients that generalized hypersensitivity reactions have been reported. Necrosis of the skin has been reported at the site of subcutaneous injection of heparin [see Warnings and Precautions (5.8), Adverse Reactions (6.1)].

**Other Medications**

Because of the risk of hemorrhage, advise patients to inform their physicians and dentists of all medications they are taking, including non-prescription medications, and before starting any new medication [see Drug Interactions (7.1)].

For more information concerning this drug, please call Fresenius Kabi USA, LLC at 1-800-551-7176.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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