HEPARIN I. V. FLUSH SYRINGE

"Heparin Lock Flush Solution, USP, Vascular Access Flush Device" is intended for intravenous injection access device only, and is not to be used for antiallergic therapy.

DESCRIPTION

Heparin I. V. Flush Syringe is a polypropylene, luer locking syringe containing Heparin Lock Flush Solution, USP, a sterile non-pyrogenic solution of heparin sodium. Heparin sodium is derived from porcine intestinal mucosa and 9 mg of sodium chloride in water for injection. The pH is between 5.0 and 7.5.

The other components are: sodium carboxymethylcellulose, sodium citrate, sodium bicarbonate, sodium citric acid, lactic acid, and dextrose. Each mL contains 10 units or 100 units of heparin sodium. The device is not made with natural rubber latex. This device is not made with DEHP. This device has no preservative and is polypropylene, luer lock syringes.

CLINICAL PHARMACOLOGY

Heparin sodium leads to the clotting of blood and the formation of fibrin clots both in vivo and in vitro. Heparin acts at multiple sites in the normal coagulation system. Small amounts of heparin sodium in combination with antithrombin III (heparin cofactor) can inhibit thrombin by inactivating activated Factor X and inhibiting the conversion of prothrombin to thrombin.

The primary antithrombotic effect of heparin sodium is the prevention of the conversion of prothrombin to thrombin. This effect occurs by inhibiting thrombin and by preventing the conversion of fibrinogen to fibrin. Heparin also prevents the formation of a stable fibrin clot by inhibiting the activation of platelets, which are essential for the conversion of fibrinogen to fibrin. Uptake of heparin sodium is followed by the release of free heparin, with the result, the results of blood coagulation tests.

Laboratory studies have achieved two to four hours following subcutaneous administration, although there are considerable individual variations. Lineprinter plots of heparin sodium plasma concentrations with time, for a wide range of dose levels, are linear which suggest the absence of zero order processes. Liver and reticuloendothelial systems are the sites of biotransformation. Significant, such thrombocytopenia can be accompanied by severe thromboembolic complications such as skin necrosis, gangrene of the extremities that may lead to amputation, myocardial infarction, pulmonary embolism, stroke and possible death.

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ADVERSE REACTIONS

Intramuscular injection of heparin sodium to treat the conditions in which increased danger of hemorrhage exist are:

Cardiovascular – Subacute bacterial endocarditis. Severe hypertension.

Gastrointestinal – Ulceration and lesions and severe thrombocytopenia.

Hematologic – Conditions associated with increased bleeding tendencies, such as hemophilia, thrombocytopenia, and some vascular purpuras.

Neurologic – Convulsions, seizures, and stroke and possible death.

Respiratory – Bronchospasm, coughing, and wheezing.

Other: Headache, dizziness, flushing, sweating, erythema, mild pain, hematoma or ulceration may follow deep subcutaneous (intrafat) injection of Heparin Lock Flush Solution.

WARNINGS

Heparin I. V. Flush Syringe should be used with extreme caution in infants and in patients with disease states in which there is an increased danger of hemorrhage.

Warnings for use of Heparin I. V. Flush 100 Units/mL concentration for neonates or infants, who weigh less than 10 Kg because of the risk of systemic anticoagulation (bleeding). Caution is necessary when using the 10 Units/mL concentration in infants who weigh less than 1 Kg who are receiving frequent flushes as this may amount to the therapeutic dose given to the infant in 24 hour period.

Heparin I. V. Flush Syringe is NOT intended for intramuscular use. Heparin sodium is not intended for intramuscular use. Heparin Lock Flush Solution.

CONTRAINDICATIONS

Heparin sodium should NOT be used in patients with an uncontrollable active bleeding state or with severe thrombocytopenia.

INDICATIONS AND USAGE

1) Heparin I. V. Flush Syringe is intended to maintain patency of an indwelling intravenous catheter device designed for intermittent injection or infusion therapy or blood sampling. Heparin I. V. Flush Syringe may be used following initial placement of the device in the vein, after each injection of the medication, or after withdrawal of blood for laboratory analysis.

2) Heparin I. V. Flush Syringe is not to be used for anticoagulant therapy.

NOTE: Heparin Lock Flush Solution.
### OVERDOSAGE

**Symptoms:** Bleeding is the chief sign of Heparin Lock Flush Solution overdose. Nosebleeds, blood in urine or tarry stools may be noted as the first sign of bleeding. Easy bruising or petechial formations may precede frank bleeding.

**Treatment:** Neutralization of heparin effect.

When clinical circumstances (bleeding) require reversal of heparinization, protamine sulfate (1% injection) by slow infusion will neutralize heparin sodium. For additional information, including warnings, precautions and dosage, consult the labeling of Protamine Sulfate injection, products.

### DOSAGE AND ADMINISTRATION

Heparin I. V. Flush Syringe is recommended for maintenance of patency of heparin lock device or central venous catheter. Noncentral use: Heparin I.V. Flush Syringe 1 Unit/mL is recommended to be used in the neonates (see WARNINGS). Geriatric Use; Patients over 60 years of age may require lower doses of heparin.

The selection of appropriate concentration of Heparin Lock Flush Solution, USP should be based on current practice standards and institutional policies and procedures.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Slight discoloration does not alter potency.

**Maintenance of patency of intravenous access devices:**

To prevent clot formation in a heparin lock device or central venous catheter following its placement. Heparin Lock Flush Solution is injected as a single dose via the injection site using a volume of solution equivalent to that of the vascular access device, in accordance with the recommendation for the volume necessary to clear the device. After each use of the vascular access device for injection or infusion of medication, or withdrawal of blood samples, another volume of Heparin Lock Flush Solution equivalent to that of the vascular access device should be used to determine the effectiveness of the heparin lock. Aspirate before administering any solution via the lock in order to confirm patency and location of the catheter tip. If the drug product to be administered is incompatible with heparin, flush all the Heparin Lock Flush Solution from the vascular access device using a suitable alternate solution before injecting or infusing the drug product. The alternate solution should be an isotonic injectable that is compatible with both the drug product and Heparin Lock Flush Solution. 0.9% Sodium Chloride Injection, USP is usually suitable for this purpose; consult product literature for confirmation. Following the administration of the incompatible drug product, the intravenous access device is again flushed with the Sodium Chloride (0.9%) Injection or appropriate compatible alternate solution, which may be followed by Heparin Lock Flush Solution.

Heparin Lock Flush Solution may also be used after each withdrawal of blood for laboratory tests. When Heparin Lock Flush Solution would interfere with or alter the results of blood tests, the Heparin Lock Flush Solution should be cleared from the device by aspirating and discarding it before the withdrawal of blood sample.

### STORAGE

Do not use if solution is discolored, cloudy, hazy, or contains a precipitate, or if the syringe is damaged. Store at 25°C (77°F); excursions permitted to 15°–30°C (59°–86°F). Do not freeze.

### DIRECTIONS FOR USE

1. Solution and fluid path are sterile and non-pyrogenic if the tip cap is in place, syringe is intact and there is no evidence of leakage. Use proper aseptic technique.

2. Inspect plastic wrapping. Do not use if plastic wrapping is damaged or not intact. (Figure 1)

3. Remove plastic packaging by tearing along perforation. (Figure 2)

4. Do not use if, solution is discolored, cloudy, hazy, or contains a precipitate, or if the syringe is damaged. (Figure 3)

5. With the tip cap of the syringe on, press the syringe forward to properly activate the syringe. Improper activation may difficult withdrawal and/or may cause plunger rod separation. Never draw back rod because the product may become contaminated. (Figure 4)

6. Remove tip cap. Hold the syringe unit upright and prime to expel any air bubble if present. (Figure 5)

7. Syringe is now ready to use. Per Intralaminated protocol attach flush syringe to access device and flush. (Figure 6)

8. When attempting to aspirate tubing or indwelling device by pulling back on the syringe plunger, while attached to the tubing or indwelling device, use two-handed technique with one hand on the syringe barrel and the other on the plunger. Pull the plunger straight back. Do not pull off the plunger end. (Figure 7)

9. Use in accordance with intravenous tubing or indwelling device manufacturer’s recommendation. (Figure 8)

### How supplied

Heparin I. V. Flush Syringe is available as follows:

<table>
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<tr>
<th>Product No.</th>
<th>NDC No.</th>
<th>MIH-2223 64253-222-23 Heparin I. V. Flush Syringe 10 units/mL; 5 mL fill in 6 mL Syringe LL</th>
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**For detailed handling information see Directions for Use section.**

**WARNINGS**

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9. Use in accordance with intravenous tubing or indwelling device manufacturer’s recommendation. (Figure 8)

Discard empty unit after use. Discard any unused portion. Do not reuse disposable syringes. (Figure 9)