Prefilled Flush Syringes
HEPARIN LOCK FLUSH SOLUTION, USP

WITH 0.9% SODIUM CHLORIDE, USP IN WATER FOR INJECTION
VASCULAR ACCESS FLUSH DEVICE | NO PRESERVATIVES | NON-PYROGENIC | STERILE

McKesson Med Stream heparin lock prefilled flush syringes are intended for maintenance of intravenous injection access device only, and they are not to be used for anticoagulant therapy.

DESCRIPTION

McKesson Med Stream heparin lock prefilled flush syringes are polypropylene, luer locking syringes containing heparin lock flush solution, USP, a sterile nonpyrogenic, isotonic injection. Each mL in a heparin lock prefilled flush syringe contains either 10 units or 100 units of heparin sodium derived from porcine intestinal mucosa and 9 mg of sodium chloride in water for injection. The pH is between 5.0 and 7.5. Heparin is a heterogeneous group of straight-chain anionic mucopolysaccharides, called glycosaminoglycans, having anticoagulant properties. Although others may be present, the main sugars contained in heparin are (1) alpha-L-iduronic acid 2-sulfate, (2) 2-deoxy-2-sulfamino-alpha–D-glucose 6-sulfate, (3) Beta-D-glucuronic acid, (4) 2-acetamido-2-deoxy-alpha-D-glucose and (5) alpha-L-iduronic acid. The device is not made with natural rubber latex. This device is not made with DEHP. This device has no preservatives and are polypropylene, luer lock syringes.

CLINICAL PHARMACOLOGY

Heparin sodium inhibits reactions that lead to the clotting of blood and the formation of fibrin clots both *in vitro* and *in vivo*. Heparin acts at multiple sites in the normal coagulation system. Small amounts of heparin sodium in combination with antithrombin III (heparin cofactor) can inhibit thrombosis by inactivating activated Factor X and inhibiting the conversion of prothrombin to thrombin. Once active thrombosis has developed, larger amounts of heparin can inhibit further coagulation by inhibiting thrombin and preventing the conversion of fibrinogen to fibrin. Heparin also prevents the formation of a stable fibrin clot by inhibiting the activation of the fibrin-stabilizing factor. The solution in the concentration of 10 units/mL may alter, and in the case of higher concentrations, will alter, the results of blood coagulation tests.

Peak plasma levels of heparin sodium are achieved two to four hours following subcutaneous administration, although there are considerable individual variations. Loglinear 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. The biphasic elimination curve, a rapidly declining alpha phase (t1/2 = 10 minutes) and after the age of 40 a slower beta phase, indicates uptake in organs. The absence of relationship between anticoagulant half-life and concentration half-life may reflect factors such as protein binding of heparin sodium.

Heparin sodium does not have fibrinolytic activity, therefore, it will not lyse existing clots.

Patients over 60 years of age, following similar doses of heparin, may have higher plasma levels of heparin and longer activated partial prothrombin time (APTTs) compared with patients under 60 years of age.

INDICATIONS AND USAGE

1. McKesson Med Stream heparin lock prefilled flush syringes are intended to maintain patency of an indwelling intravenous catheter device designed for intermittent injection or infusion therapy or blood sampling. McKesson Med Stream heparin lock prefilled flush syringes 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. McKesson Med Stream heparin lock prefilled flush syringes are not to be used for anticoagulant therapy.

CONTRAINDICATIONS

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

WARNINGS

McKesson Med Stream heparin lock prefilled flush syringes should be used with extreme caution in infants and in patients with disease states in which there is an increased danger of hemorrhage.

Neonatologists do not advise the use of heparin lock flush solution with 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 premature 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.

McKesson Med Stream heparin lock prefilled flush syringe is NOT intended for intramuscular use.

Re-use of single- use devices creates a potential risk of patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

Hypersensitivity: Patients with documented hypersensitivity to heparin or pork products should not receive heparin lock flush solution

Thrombocytopenia: Thrombocytopenia has been reported to occur in patients receiving heparin sodium with a reported incidence of 0% to 30%. Mild Thrombocytopenia (count greater than 100,000mm3) may remain stable or reverse even if heparin sodium is continued. However, Thrombocytopenia of any degree should be monitored closely. If the count falls below 100,000/mm3 or if recurrent thrombosis develops, heparin sodium should be discontinued. If continued heparin sodium is essential, use of heparin from a different organ source can be reinstituted with caution.

Discontinue use if coagulation test is unduly prolonged, or if hemorrhage or thrombocytopenia occurs.

Use with extreme caution in infants and in patients with disease states in which there is an increased danger of hemorrhage.

Some of the conditions in which increased danger of hemorrhage exist are:
Cardiovascular – Subacute bacterial endocarditis. Severe hypertension.
Surgical – During and immediately following (a) spinal tap or spinal anesthesia or (b) major surgery, especially involving the brain, spinal cord or eye.
Hematologic – Conditions associated with increased bleeding tendencies, such as hemophilia, thrombocytopenia, and some vascular purpuras.
Gastrointestinal – Ulcerative lesions and continuous tube drainage of the stomach or small intestine.
Other – Menstruation, liver disease with impaired hemostasis.

PRECAUTIONS

White Clot Syndrome: It has been reported that patients on heparin sodium may develop new thrombus formation in association with Thrombocytopenia resulting from irreversible aggregation of platelets induced by heparin. The process may lead to severe thromboembolic complications: skin necrosis, gangrene of the extremities that may lead to amputation, myocardial infarction, pulmonary embolism, stroke and possibly death. Therefore, heparin sodium use should be promptly discontinued if a patient develops new thrombosis in association with thrombocytopenia.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term studies in animals have been performed to evaluate the carcinogenic potential of heparin sodium. No reproductive studies in animals have been performed concerning mutagenesis or impairment of fertility.

Pregnancy: Pregnancy Category C: Teratogenic Effects: Animal reproduction studies have not been conducted with heparin sodium. It is also not known whether heparin sodium can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Heparin sodium should be given to a pregnant woman only if clearly needed.

Nonteratogenic Effects: Heparin sodium does not cross the placental barrier.

Nursing Mothers: Heparin sodium is not excreted in human milk. Caution must be exercised to avoid pharmacological effects of heparin. Consideration should be given to the cumulative amounts of heparin received from the frequent administration of heparin lock flush solution during a 24-hour period, especially in infants and the elderly.

Increased risk in older patients, especially women: A higher incidence of bleeding has been reported in patients, particularly women, over 60 years of age.

Geriatric use: A higher incidence of bleeding has been reported in patients over 60 years of age, especially women (see Precautions). Clinical studies indicate that lower doses of heparin may be indicated in these patients (see Clinical Pharmacology and Dosage and Administration).

Laboratory tests: Periodic platelet counts, hematocrits and tests for occult blood in stool are recommended during the entire period of use of heparin lock flush solution.

General: Caution must be exercised to avoid any contact between heparin lock flush solution and incompatible drugs. Consult appropriate literature for compatibility data before mixing heparin lock flush solution with any drug product. Do not administer if a precipitate appears, or if Solution is cloudy or hazy or if the syringe is damaged. For single use only. Discard any unused portion. McKesson MedStream heparin lock prefilled flush syringes should be used with caution in patients receiving drugs such as aspirin, dextran, phenylbutazone, ibuprofen, indomethacin, dipyridamole, hydroxychloroquine, and others that interfere with platelet reactions (the hemostatic defense of heparinized patients). These drugs may induce bleeding in patients receiving heparin.

ADVERSE REACTIONS

Hemorrhage: Hemorrhage is the chief complication that may result from heparin sodium. Discontinuing heparin sodium use can usually control an overly prolonged clotting time or minor bleeding during heparin use. Bleeding can occur at any site, but certain specific hemorrhagic complications may be difficult to detect.

Hypersensitivity: Generalized hypersensitivity reactions have been reported, with chills, fever, and urticaria as the most usual manifestations, and asthma, rhinitis, lacrimation, headache, nausea and vomiting, and anaphylactoid reactions, including shock, occurring more rarely. Itching and burning, especially on the plantar side of the feet, may occur.

Thrombocytopenia has been reported to occur in patients with a reported incidence of 0% to 30%. While often mild and of no obvious clinical significance, 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. Certain episodes of painful, ischemic and cyanosed limbs have in the past been attributed to allergic vasospastic reactions. Whether these are in fact identical to the thrombocytopenia-associated complications remain to be determined.

Local Irritation, erythema, mild pain, hematoma or ulceration may follow deep subcutaneous (intrafat) injection of McKesson MedStream heparin lock prefilled flush syringes. These complications are much more common after intramuscular use, and such use is not recommended.

OVERDOSAGE

Symptoms: Bleeding is the chief sign of heparin lock flush solution overdosage. 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

McKesson Med Stream heparin lock prefilled flush syringes are recommended for maintenance of patency of heparin lock device or central venous catheter.
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.

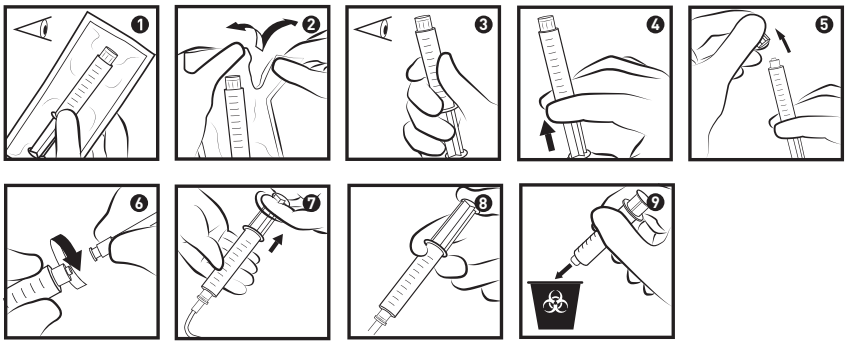
Maintenance of patency of intravenous access devices:
To prevent clot formation in a heparin lock device or central venous catheter following its placement. Heparin lock flush solution is injected as a single dose via the injection site using a volume of solution equivalent to that of the vascular access 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 injected to restore 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 injection 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.

Withdrawal of blood samples:
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.

INSTRUCTIONS 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 syringe use and/or may cause plunger rod separation. Never draw back the plunger rod as 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 institutional 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 or bend the plunger sideways. (Figure 7)

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

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

HOW SUPPLIED

McKesson Med Stream heparin lock prefilled flush syringes are available as follows:

MFR#			
191-MIH-2233	HEPARIN LOCK FLUSH SOLUTION, USP	10 UNITS/mL	3 mL FILL | 12 mL SYRINGE
191-MIH-2235	HEPARIN LOCK FLUSH SOLUTION, USP	10 UNITS/mL	5 mL FILL | 12 mL SYRINGE
191-MIH-3333	HEPARIN LOCK FLUSH SOLUTION, USP	100 UNITS/mL	3 mL FILL | 12 mL SYRINGE
191-MIH-3335	HEPARIN LOCK FLUSH SOLUTION, USP	100 UNITS/mL	5 mL FILL | 12 mL SYRINGE

Above products are available in boxes of 60 counts each.

CAUTION

This device's solution and its pathway are sterile. Do not place the device on sterile field.
Federal (USA) law restricts this device to sale by or on order of a physician.

Questions? Call 1-800-777-4908

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