

Changes to the USP Heparin Sodium Monograph

In response to the heparin adulteration situation of 2007/2008, USP has worked swiftly to improve the standards for unfractionated heparin (UFH) in order to secure the supply of safe heparin and heparin products in the U.S. (Source: USP homepage www.usp.org)

What is the USP?

The USP (United States Pharmacopeia) is an official public standards-setting authority for all prescription and over the counter medications and other healthcare products manufactured or sold in the United States. USP sets standards for the quality, purity, strength and consistency of these products. It is a non-governmental, not-for-profit organization whose independent volunteer experts work under strict conflict-of-interest rules to set scientific standards. Volunteers come from pharmacy, medicine, academia, pharmaceutical and food industries, health plans and consumer organizations. (Source: USP homepage www.usp.org)

Why did USP change the standard for Heparin Sodium?

Over the past two years, there has been an increase in the prevalence of adulterated heparin. USP acted to improve the standard for unfractionated heparin (UFH) to ensure a safe supply of heparin in the U.S. USP has implemented monograph changes in a phased approach. Stage 1 revisions occurred in early 2008 and aimed to ensure a safe heparin supply. Stage 2 changes were pursued to provide additional assurances. The new standard is effective October 1, 2009.

What has changed?

The testing methods for Heparin Sodium USP have changed. All Hospira heparin product formulations have not changed.

What testing has changed?

The new method provides greater sensitivity and is more specific.

Will this affect all heparin products?

Yes, this will affect all heparin products manufactured by Hospira and other heparin manufacturers. Hospira's presentations consist of small and large volume parenterals, including fliptop vials, and premixed flexible containers for infusion.

Is Hospira in compliance with the new USP standards?

Hospira is in compliance with this new standard.

Will the labeling change for the heparin products?

Labelling will not change.

Will the dosing change?

The revised USP reference standard and unit definition for heparin is about 10 percent less potent than the former USP unit. For additional information see <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm184674.htm>. There are no changes to the package insert regarding heparin dosing.



Will monitoring change?

The APTT (activated partial thromboplastin time) and ACT (activated clotting time) will continue to be used for monitoring patients.

Will protocols involving Heparin change?

This will be determined at the institutional level.

How can a clinician determine if the Hospira Heparin product was manufactured under the new standard?

Heparin products manufactured by Hospira under the new standard will have a lot number beginning with 82 or higher. Please see the representative product labels for lot number placement following the Q & A.

When will Hospira start manufacturing Heparin under the new standard?

Hospira products manufactured as of October 1, 2009, will meet the new standard.

Will Hospira continue to sell product manufactured under the previously approved USP standards?

Yes.

Are old products safe to use?

Yes.

Will there be a need to have any product recalled as a result of the October 1, 2009, USP change?

No.

Are Heparin Sodium products manufactured under the previously approved USP standards considered safe?

Yes. It is currently approved product for sale.

Can customers specify they only want to order Heparin manufactured under the new standard?

Customers work with their account managers to request Heparin manufactured under the new USP monograph standards; however, heparin products manufactured before this USP change are safe and efficacious to use.

When will heparin finished product compliant with the October 1, 2009, USP standards be available for sale?

It is product-dependent, but generally in December 2009.

Where can medical inquiries be directed?

Medical inquiries can be directed to Hospira at **1-866-488-6088, Option 4.**



For All Products

If the **first two digits of the Lot # are greater than or equal to 82**, the product is manufactured in compliance with the USP October 1, 2009, Monograph updates.

≥ 82

LOT 82-###-XX

EXP DD MMM YYYY

500 mL N° 07620250 DIN 01990748

HEPARIN Sodium/HÉPARINE sodique
1000 USP units/unités USP (2 USP units/unités USP/mL)
in 0.9% Sodium Chloride Injection/
dans du chlorure de sodium à 0,9% injectables

4

Inspect bag by squeezing firmly. If leaks are found, discard. Storage: 20 to 25°C (see "Controlled Room Temperature" in USP). Protect from freezing.

3

ANTICOAGULANT FOR I.V. USE • STERILE • NONPYROGENIC • SINGLE-DOSE

100 mL: Heparin sodium 200 USP heparin units (porcine intestinal mucosa), sodium chloride 0.9 g and, as buffers, citric acid H₂O 40 mg, dibasic sodium phosphate 7H₂O 434 mg. Usual Dose: See insert. Use only if solution is clear. Discard unused portion. Caution: Must not be used in series connections. Do not add any additive to the solution.

2

378 mOsm/L pH approx. 7 Electrolytes mmol (mEq)/L:
Na 186.4; Cl 154; HPO₄ 16.2 (32.4); Citrate 2.1 (5.7)

Inspecter le sac en le comprimant. Jeter en cas de fuites. Entreposage: 20 à 25°C (voir "Controlled Room Temperature" dans l'USP). Craint le gel.

1

ANTICOAGULANT-ADMINISTRATION I.V. • STÉRILE • APYROGÈNE • UNIDOSE

100 mL: héparine sodique 200 unités d'héparine USP (muqueuse intestinale du porc), chlorure de sodium 0,9 g et, comme tampons, acide citrique H₂O 40 mg, phosphate disodique 7H₂O 434 mg. Posologie usuelle: voir dépliant. N'utiliser que si la solution est limpide. Jeter tout reste. Attention: Ne pas utiliser dans les montages en série. N'ajouter aucun additif à la solution.



(01)08821357620008

IM-1822 (1/09)

Montréal, QC H4M 2X6 Hospira

PVC CONTAINER
CONTENANT DE PVC



≥ 82

LOT 82-###-XX

EXP DD MMM YYYY

500 mL N° 07760250 DIN 00894648

HEPARIN Sodium/HÉPARINE sodique
20 000 USP units/unités USP (40 USP units/unités USP/mL)
in 5% Dextrose Injection / dans du dextrose à 5% injectables

Inspect bag by squeezing firmly. If leaks are found, discard. Storage: 20 to 25°C (see "Controlled Room Temperature" in USP). Protect from freezing.

ANTICOAGULANT FOR INTRAVENOUS USE • STERILE • NONPYROGENIC • SINGLE-DOSE

100 mL: Heparin sodium 4000 USP heparin units (porcine intestinal mucosa), dextrose H₂O 5 g, citric acid anhydrous 51 mg and dibasic sodium phosphate anhydrous 103 mg (as buffers), sodium metabisulfite 20 mg (antioxidant). **Usual Dose:** See insert. Use only if solution is clear. Discard unused portion. **Caution: Must not be used in series connections. Do not add any additive to the solution.**

287 mOsm/L pH approx. 5.4
Electrolytes mmol (mEq)/L: Na 16 (17); HPO₄ 7 (15); Citrate 3 (8)

Inspecter le sac en le comprimant. Jeter en cas de fuites. Entreposage: 20 à 25°C (voir "Controlled Room Temperature" dans l'USP). Craint le gel.

ANTICOAGULANT - ADMINISTRATION I.V. • STÉRILE • APYROGÈNE • UNIDOSE

100 mL: héparine sodique 4000 unités d'héparine USP (muqueuse intestinale du porc), dextrose H₂O 5 g, acide citrique anhydre 51 mg et phosphate disodique anhydre 103 mg (comme tampons), métabisulfite de sodium 20 mg (antioxydant). **Posologie usuelle:** voir dépliant. N'utiliser que si la solution est limpide. Jeter tout reste. **Attention: Ne pas utiliser dans les montages en série. N'ajouter aucun additif à la solution.**

IM-1824 (1/09)

Montréal, QC H4M 2X6 Hospira

PVC CONTAINER
CONTENANT DE PVC

LATEX



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1

≥ 82

LOT 82-###-XX

EXP DD MMM YYYY

500 mL N° 07761250 DIN 00894605

HEPARIN Sodium/HÉPARINE sodique

25 000 USP units/unités USP (50 USP units/unités USP/mL)

in 5% Dextrose Injection / dans du dextrose à 5% injectables

Inspect bag by squeezing firmly. If leaks are found, discard. Storage: 20 to 25°C (see "Controlled Room Temperature" in USP). Protect from freezing.

ANTICOAGULANT FOR INTRAVENOUS USE • STERILE • NONPYROGENIC • SINGLE-DOSE

100 mL: Heparin sodium 5000 USP heparin units (porcine intestinal mucosa), dextrose H₂O 5 g, citric acid anhydrous 51 mg and dibasic sodium phosphate anhydrous 103 mg (as buffers), sodium metabisulfite 20 mg (antioxidant). **Usual Dose:** See insert. Use only if solution is clear. Discard unused portion. **Caution:** Must not be used in series connections. Do not add any additive to the solution.

287 mOsm/L pH approx. 5.4
Electrolytes mmol (mEq)/L: Na 16 (17); HPO₄ 7 (15); Citrate 3 (8)

Inspecter le sac en le comprimant. Jeter en cas de fuites. Entreposage: 20 à 25°C (voir "Controlled Room Temperature" dans l'USP). Craint le gel.

ANTICOAGULANT - ADMINISTRATION I.V. • STÉRILE • APYRÈNE • UNIDOSE

100 mL: héparine sodique 5000 unités d'héparine USP (muqueuse intestinale du porc), dextrose H₂O 5 g, acide citrique anhydre 51 mg et phosphate disodique anhydre 103 mg (comme tampons), métabisulfite de sodium 20 mg (antioxydant). **Posologie usuelle:** voir dépliant. N'utiliser que si la solution est limpide. Jeter tout reste. **Attention:** Ne pas utiliser dans les montages en série. N'ajouter aucun additif à la solution.

01)088821357761008



IM-1825 (1/09)

Montréal, QC H4M 2X6 Hospira

PVC CONTAINER
CONTENANT DE PVC



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≥ 82

LOT 82-###-XX

EXP DD MMM YYYY

1000 mL N° 07620254 DIN 01990748

HÉPARIN Sodium
HÉPARINE sodique
2000 USP units/unités USP
(2 USP units/mL /
2 unités USP/mL)

in 0.9% Sodium Chloride Injection/
dans du chlorure de sodium à 0,9%
injectables

9
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8
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7
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6

Inspect bag by squeezing firmly. If leaks are found, discard. Storage: 20 to 25°C (see "Controlled Room Temperature" in USP). Protect from freezing.

ANTICOAGULANT FOR INTRAVENOUS USE •
STERILE • NONPYROGENIC • SINGLE-DOSE

100 mL: Heparin sodium 200 USP heparin units (porcine intestinal mucosa), sodium chloride 0.9 g and, as buffers, citric acid H₂O 40 mg, dibasic sodium phosphate 7H₂O 434 mg. Usual Dose: See insert. Use only if solution is clear. Discard unused portion. Caution: Must not be used in series connections. Do not add any additive to the solution.

378 mOsm/L pH approx. 7
Electrolytes mmol (mEq)/L: Na 186.4; Cl 154;
HPO₄ 16.2 (32.4); Citrate approx. 2.1 (5.7)

Inspecter le sac en le comprimant. Jeter en cas de fuites. Entreposage: 20 à 25°C (voir "Controlled Room Temperature" dans l'USP). Craint le gel.

ANTICOAGULANT - ADMINISTRATION I.V. •
STERILE • APYROGÈNE • UNIDOSE

100 mL: héparine sodique 200 unités d'héparine USP (muqueuse intestinale du porc), chlorure de sodium 0,9 g et, comme tampons, acide citrique H₂O 40 mg, phosphate disodique 7H₂O 434 mg. Posologie usuelle: voir dépliant. N'utiliser que si la solution est limpide. Jeter tout reste. Attention: Ne pas utiliser dans les montages en série. N'ajouter aucun additif à la solution.

5
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Hospira
Montréal, QC H4M 2X6

PVC CONTAINER
CONTENANT DE PVC **LATEX**
IM-1823 (1/09)

10 mL Multidose Sterile/ Stérile	DIN 00725323 N° 01151	Derived from porcine intestinal mucosa. NOT FOR ANTICOAGULANT THERAPY. Composition and Dosage: See insert. Contains 9 mg/mL benzyl alcohol (as preservative). Provenant de la muqueuse intestinale du porc. NE PAS UTILISER COMME ANTICOAGULANT. Composition et posologie: voir le dépliant. Contient 9 mg/mL d'alcool benzylique (comme préservateur). RL-2812 Montréal, QC H4M 2X6 Hospira
Heparin Lock Flush Solution USP		 (01) 08821351151003 LOT 82-##-XX EXP DD MMM YYYY
100 USP Units/10 mL (10 USP Units/mL)		
USE CAUTIOUSLY IN NEWBORNS EMPLOYER AVEC PRUDENCE CHEZ LES NOUVEAU-NÉS		

≥ 82



10 mL Multidose Sterile/ DIN 00725315
Stérile N° 01152

**Heparin Lock Flush
Solution USP**

1000 USP Units/10 mL
(100 USP Units/mL)

**USE CAUTIOUSLY IN NEWBORNS
EMPLOYER AVEC PRUDENCE
CHEZ LES NOUVEAU-NÉS**

Derived from porcine intestinal mucosa.

NOT FOR ANTICOAGULANT THERAPY.

Composition and Dosage: See insert. Contains 9 mg/mL benzyl alcohol (as preservative).

Provenant de la muqueuse intestinale du porc.
NE PAS UTILISER COMME ANTICOAGULANT.

Composition et posologie: voir le dépliant.

Contient 9 mg/mL d'alcool benzylique (comme préservateur).

RL-2813

Montréal, QC H4M 2X6 Hospira



LOT 82-##-XX

EXP DD MMM YYYY



≥ 82

25 x 10 mL Multidose Vials Sterile DIN 00725323 Hospira
 N° 01151010

Heparin Lock Flush
 Solution USP

**USE CAUTIOUSLY
 IN NEWBORNS**

For maintenance of potency of intravenous injection devices only. Not to be used for anti-coagulant therapy.

LOT 82-###-XX
 EXP DD MMM YYYY



180

**EMPLOYER AVEC PRUDENCE
 CHEZ LES NOUVEAU-NÉS**

Pour le maintien de la perméabilité des dispositifs d'injection intraveineuse seulement. Ne pas utiliser comme traitement anticoagulant.

DIN 00725323 Stérile Hospira
 N° 01151010

**Solution de rinçage
 héparinée usp**

100 unités USP/10 mL
 (10 unités USP/mL)

CA-2173

25 x 10 mL Flacons multidoses Stérile N° 01151010 DIN 00725323

Solution de rinçage héparinée USP

100 unités USP/10 mL
 (10 unités USP/mL)

**EMPLOYER AVEC PRUDENCE
 CHEZ LES NOUVEAU-NÉS**

Hospira Healthcare Corporation
 Corporation de soins de santé Hospira
 Montréal, QC H4M 2X6

25 x 10 mL Flacons multidoses Stérile N° 01151010 DIN 00725323

Solution de rinçage héparinée USP

100 unités USP/10 mL
 (10 unités USP/mL)

**EMPLOYER AVEC PRUDENCE
 CHEZ LES NOUVEAU-NÉS**

Hospira Healthcare Corporation
 Corporation de soins de santé Hospira
 Montréal, QC H4M 2X6

25 x 10 mL Multidose Vials Sterile DIN 00725323 Hospira
 N° 01151010

Heparin Lock Flush
 Solution USP

100 USP units/10 mL
 (10 USP units/mL)

Storage: Store between 20 and 25°C. Protect from freezing. May contain NaOH for pH adjustment.



(01)18821351151000

Hospira Healthcare Corporation
 Corporation de soins de santé Hospira
 Montréal, QC H4M 2X6

≥ 82

25 x 10 mL Multidose Vials Sterile DIN 00725315  **LOT 82-### XX**
 N° 01152010 **EXP DD MMM YYYY**

Heparin Lock Flush Solution USP

1000 USP units/10 mL
(100 USP units/mL)

USE CAUTIOUSLY IN NEWBORNS

For maintenance of potency of intravenous injection devices only. Not to be used for anti-coagulant therapy.



232

25 x 10 mL Flacons multidosés **Sterile** **DIN 00725315**  **N° 01152010**

Solution de rinçage héparinée USP


1000 unités USP/10 mL
(100 unités USP/mL)

EMPLOYER AVEC PRUDENCE CHEZ LES NOUVEAU-NÉS

Pour le maintien de la perméabilité des dispositifs d'injection intraveineuse seulement. Ne pas utiliser comme traitement anticoagulant.

Entreposage: Conserver entre 20 et 25 °C. **Craint le gel.** Peut contenir du NaOH pour l'ajustement du pH.


CA-2177

25 x 10 mL Multidose Vials **Sterile** **DIN 00725315**  **N° 01152010**

Heparin Lock Flush Solution USP

1000 USP units/10 mL
(100 USP units/mL)

Storage: Store between 20 and 25 °C. **Protect** from freezing. May contain NaOH for pH adjustment.



(01) 18821351152007

Hospira Healthcare Corporation
 Corporation de soins de la santé Hospira
 Montréal, QC H4M 2X6

25 x 10 mL Flacons multidosés **Sterile** **N° 01152010** **DIN 00725315**

Solution de rinçage héparinée USP

1000 unités USP/10 mL
(100 unités USP/mL)

EMPLOYER AVEC PRUDENCE CHEZ LES NOUVEAU-NÉS

Hospira Healthcare Corporation
 Corporation de soins de la santé Hospira
 Montréal, QC H4M 2X6