



May 18, 2012

Important Safety Information Regarding Carpuject Syringe System – Potential Overfill
ACTION REQUIRED

Dear Healthcare Professional,

Hospira is issuing this Important Safety Information letter to alert Healthcare Professionals to the potential overfill of volume amounts in the pre-filled Carpuject syringe system. This also includes the 2 mL iSecure presentations of midazolam and ondansetron. Hospira has received reports of Carpuject syringes containing more than the labeled fill volume of medication than is stated on the label. See attached for list of affected products and lots.

Healthcare professionals should visually inspect the fill volume in the pre-filled Carpuject syringe and verify that it matches the labeled volume to ensure patients receive the prescribed amount of medication. See attached photos for examples of correctly filled cartridge volumes. Overfilled syringes can lead to accidental overdose which could have significant impact on patients resulting in life-threatening consequences.

The root cause has been identified as a manufacturing issue in the filling equipment and corrective actions have been implemented to prevent further occurrence. To date, no adverse events have been reported. At this time, although it is believed that the potential for overfill occurrence (where the syringe contains more than the labeled fill volume) is low, medication overfill has been reported.

Directions for Healthcare Providers

Before administration visually inspect and confirm the Carpuject syringe contains the labeled fill volume. On inspection, if an overfilled Carpuject syringe is detected, the unit should not be used. The clinician should report the incident to Hospira, Inc. and include specific product information and lot number. The Carpuject syringe should be returned to Hospira for evaluation.

For medical inquiries, please contact Hospira Medical Communications at 1-800-615-0187 (24 hours a day, seven days a week) or e-mail Medcom@hospira.com. To report product complaints, such as an overfilled Carpuject or adverse events call 1-800-441-4100 or e-mail productcomplaintspp@hospira.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

Sincerely,

A handwritten signature in cursive script that reads "Steven Pregulman MD".

Steven Pregulman, MD
Global Medical Director
Global Clinical Research and Development and Medical Affairs

NDC / PRODUCT	LOT	EXP		LOT	EXP		LOT	EXP
0409-2287-31 Ketorolac Tromethamine Inj., USP, 30 mg/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	04205LL	1 OCT 2012						
0409-1176-30 Demerol™ (Meperidine HCl Inj., USP) 2.5% 25 mg/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	93650LL	1 SEP 2012		93655LL	1 SEP 2012		95740LL	1 NOV 2012
	95735LL	1 NOV 2012		01500LL	1 JAN 2013		01745LL	1 JAN 2013
	01815LL	1 JAN 2013		02745LL	1 FEB 2013		02750LL	1 FEB 2013
	03760LL	1 MAR 2013		03765LL	1 MAR 2013			
0409-1273-32 Diazepam Inj., USP 5 mg/mL, 2 mL in 2.5 mL Carpuject™, Luer Lock								
	96600LL	1 JUN 2012		02530LL	1 AUG 2012		03600LL	1 SEP 2012
	03790LL	1 SEP 2012		03660LL	1 SEP 2012		04770LL	1 OCT 2012
	04810LL	1 OCT 2012		05780LL	1 MAY 2013		12635LL	1 JUN 2013
	12590LL	1 JUN 2013		12595LL	1 JUN 2013		12640LL	1 JUN 2013
	13575LL	1 JUL 2013		13585LL	1 JUL 2013		14730LL	1 AUG 2013
0409-1178-30 Demerol™ (Meperidine HCl Inj., USP) 50 mg/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	93665LL	1 SEP 2012		93660LL	1 SEP 2012		95745LL	1 NOV 2012
	95750LL	1 NOV 2012		01800LL	1 JAN 2013		01805LL	1 JAN 2013
	10625LL	1 OCT 2013		10840LL	1 OCT 2013			
0409-1179-30 Demerol™ (Meperidine HCl Inj., USP) 75 mg/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	01790LL	1 JAN 2013		01795LL	1 JAN 2013		02765LL	1 FEB 2013
0409-1276-32 Fentanyl Citrate Inj., USP 50 mcg/mL, 2 mL in 2.5 mL Carpuject™, Luer Lock								
	02720LL	1 AUG 2012		03550LL	1 SEP 2012		03625LL	1 SEP 2012
	04625LL	1 OCT 2012		06755LL	1 DEC 2012		06775LL	1 DEC 2012
	07675LL	1 JAN 2013		07680LL	1 JAN 2013		10630LL	1 APR 2013
	11695LL	1 MAY 2013		12695LL	1 JUN 2013		12705LL	1 JUN 2013
	13535LL	1 JUL 2013		13695LL	1 JUL 2013		13530LL	1 JUL 2013
	14500LL	1 AUG 2013		14535LL	1 AUG 2013		96550LL	1 JUN 2012
	02570LL	1 AUG 2012						
0409-1280-31 Heparin Lock Flush Solution, USP, 10 USP Units/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	92585LL	1 AUG 2012						
0409-1402-31 Heparin Sodium Inj., USP, 5000 USP Units/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	90860LL	1 JUN 2012						
0409-1281-31 Heparin Lock Flush Solution, USP, 100 USP Units/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	11855LL	1 NOV 2013						
0409-1281-33 Heparin Lock Flush Solution, USP, 100 USP Units/mL, 3 mL in 5 mL Carpuject™, Luer Lock								
	95705LL	1 NOV 2012		07725LL	1 JUL 2013			
0409-1280-35 Heparin Lock Flush Solution, USP, 10 USP Units/mL, 5 mL in 5 mL Carpuject™, Luer Lock								
	95510LL	1 NOV 2012						

NDC / PRODUCT	LOT	EXP		LOT	EXP		LOT	EXP
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0409-1281-35 Heparin Lock Flush Solution, USP, 100 USP Units/mL, 0.5 mL in 5 mL Carpuject™, Luer Lock								
	91535LL	1 JUL 2012						

0409-1316-32 Heparin Sodium Inj., USP, 10,000 USP Units/mL, 5 mL in 5 mL Carpuject™, Luer Lock								
	96605LL	1 JUN 2012		96630LL	1 JUN 2012		96670LL	1 JUN 2012
	01740LL	1 JUL 2012		01735LL	1 JUL 2012		01600LL	1 JUL 2012
	01680LL	1 JUL 2012		01785LL	1 JUL 2012		02535LL	1 AUG 2012
	02550LL	1 AUG 2012		02715LL	1 AUG 2012		02610LL	1 AUG 2012
	02710LL	1 AUG 2012		02740LL	1 AUG 2012		02735LL	1 AUG 2012
	02725LL	1 AUG 2012		02780LL	1 AUG 2012		03735LL	1 SEP 2012
	03810LL	1 SEP 2012		04795LL	1 OCT 2012		04645LL	1 OCT 2012
	04640LL	1 OCT 2012		04720LL	1 OCT 2012		04715LL	1 OCT 2012
	05660LL	1 NOV 2012		05545LL	1 NOV 2012		05765LL	1 NOV 2012
	05610LL	1 NOV 2012		05575LL	1 NOV 2012		05615LL	1 NOV 2012
	05795LL	1 NOV 2012		05800LL	1 NOV 2012		05820LL	1 NOV 2012
	06700LL	1 DEC 2012		06725LL	1 DEC 2012		06830LL	1 DEC 2012
	06820LL	1 DEC 2012		06735LL	1 DEC 2012		06815LL	1 DEC 2012
	06810LL	1 DEC 2012		06825LL	1 DEC 2012		07575LL	1 JAN 2013
	07576LL	1 JAN 2013		07715LL	1 JAN 2013		07730LL	1 JAN 2013
	08885LL	1 FEB 2013		08905LL	1 FEB 2013		08530LL	1 FEB 2013
	08715LL	1 FEB 2013		08685LL	1 FEB 2013		08750LL	1 FEB 2013
	08785LL	1 FEB 2013		09750LL	1 MAR 2013		09540LL	1 MAR 2013
	09595LL	1 MAR 2013		09620LL	1 MAR 2013		09760LL	1 MAR 2013
	09625LL	1 MAR 2013		09765LL	1 MAR 2013		09675LL	1 MAR 2013
	09680LL	1 MAR 2013						

0409-1283-31 Hydromorphone HCl Inj., USP 1 mg/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	07548LL	1 JUL 2013		08955LL	1 AUG 2013		09715LL	1 SEP 2013
	09720LL	1 SEP 2013		09770LL	1 SEP 2013		09725LL	1 SEP 2013
	11605LL	1 NOV 2013		11745LL	1 NOV 2013		11770LL	1 NOV 2013

0409-1312-30 Hydromorphone HCl Inj., USP 2 mg/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	11795LL	1 NOV 2013		11810LL	1 NOV 2013		11805LL	1 NOV 2013
	11840LL	1 NOV 2013		11800LL	1 NOV 2013		11815LL	1 NOV 2013
	11820LL	1 NOV 2013		12625LL	1 DEC 2013		12720LL	1 DEC 2013

0409-1304-31 Hydromorphone HCl Inj., USP 4 mg/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	92740LL	1 AUG 2012		92745LL	1 AUG 2012		94750LL	1 OCT 2012
	94755LL	1 OCT 2012		96610LL	1 DEC 2012		96645LL	1 DEC 2012
	96640LL	1 DEC 2012		01665LL	1 JAN 2013		03610LL	1 MAR 2013
	03780LL	1 MAR 2013		05705LL	1 MAY 2013		05815LL	1 MAY 2013
	11705LL	1 NOV 2013		11825LL	1 NOV 2013			

0409-2339-34 Labetalol Hydrochloride Inj., USP, 5 mg/mL, 4 mL in 5 mL Carpuject™, Luer Lock								
	90585LL	1 JUN 2012		91730LL	1 JUL 2012		93720LL	1 SEP 2012
	94790LL	1 OCT 2012		94805LL	1 OCT 2012		01720LL	1 JAN 2013
	01775LL	1 JAN 2013		01655LL	1 JAN 2013		02695LL	1 FEB 2013
	02585LL	1 FEB 2013		03825LL	1 MAR 2013		03715LL	1 MAR 2013
	03725LL	1 MAR 2013		05740LL	1 MAY 2013		08575LL	1 AUG 2013
	08900LL	1 AUG 2013		09700LL	1 SEP 2013		09730LL	1 SEPT 2013
	10775LL	1 OCT 2013		10875LL	1 OCT 2013		11690LL	1 NOV 2013
	11765LL	1 NOV 2013		12605LL	1 DEC 2013			

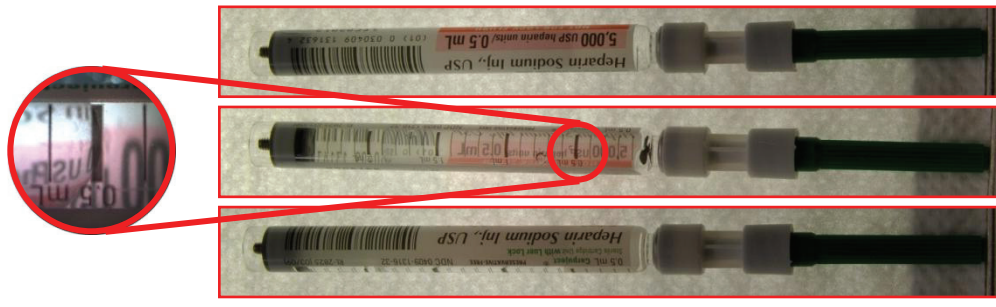
NDC / PRODUCT	LOT	EXP		LOT	EXP		LOT	EXP
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0409-1985-30 Lorazepam Inj., USP, 2 mg/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	90640LL	1 JUN 2012		90715LL	1 JUN 2012		90815LL	1 JUN 2012
	90865LL	1 JUN 2012		90866LL	1 JUN 2012		91505LL	1 JUL 2012
	92670LL	1 AUG 2012		93771LL	1 SEP 2012		93585LL	1 SEP 2012
	94710LL	1 OCT 2012		95560LL	1 NOV 2012		95580LL	1 NOV 2012
	95585LL	1 NOV 2012		96665LL	1 DEC 2012		96635LL	1 DEC 2012
	01710LL	1 JAN 2013		01545LL	1 JAN 2013		03665LL	1 MAR 2013
	03770LL	1 MAR 2013		04780LL	1 APR 2013		04595LL	1 APR 2013
	03580LL	1 MAR 2013		04755LL	1 APR 2013		04790LL	1 APR 2013
	05735LL	1 MAY 2013		05730LL	1 MAY 2013		05760LL	1 MAY 2013
	05810LL	1 MAY 2013		06575LL	1 JUN 2013		06690LL	1 JUN 2013
	07520LL	1 JUN 2013		07650LL	1 JUL 2013		08610LL	1 AUG 2013
	08525LL	1 AUG 2013		08945LL	1 AUG 2013		09590LL	1 SEP 2013
	09535LL	1 SEP 2013		09660LL	1 SEP 2013		09665LL	1 SEP 2013
	10550LL	1 OCT 2013		10850LL	1 OCT 2013		10605LL	1 OCT 2013
	10650LL	1 OCT 2013		11740LL	1 NOV 2013		12610LL	1 DEC 2013
	13675LL	1 JAN 2014		13715LL	1 JAN 2014		13730LL	1 JAN 2014
	14635LL	1 FEB 2014		14735LL	1 FEB 2014			
0409-1258-30 Morphine Sulfate Inj., USP 4 mg/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	10810LL	1 APR 2013		10815LL	1 APR 2013		10825LL	1 APR 2013
	10800LL	1 APR 2013		10855LL	1 APR 2013		10805LL	1 APR 2013
	10860LL	1 APR 2013		10820LL	1 APR 2013		11730LL	1 MAY 2013
	11735LL	1 MAY 2013		11830LL	1 MAY 2013		12515LL	1 JUN 2013
	12510LL	1 JUN 2013		13705LL	1 JUL 2013			
0409-1260-69 Morphine Sulfate Inj., USP 8 mg/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	96595LL	1 JUN 2012		01810LL	1 JUL 2012		04585LL	1 OCT 2012
	14625LL	1 AUG 2013						
0409-1261-30 Morphine Sulfate Inj., USP 10 mg/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	12725LL	1 DEC 2013		12730LL	1 DEC 2013			
0409-1264-31 Morphine Sulfate Inj., USP 15 mg/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	93765LL	1 SEP 2012		06590LL	1 JUN 2013			
0409-1778-35 Metoprolol Tartrate Inj., USP, 1 mg/mL, 5 mL in 5 mL Carpuject™, Luer Lock								
	92550LL	1 AUG 2012		11600LL	1 NOV 2013			
0409-1918-32 Preservative-Free 0.9% Sodium Chloride Inj., USP, 2 mL in 2.5 mL Carpuject™, Luer Lock								
	90835LL	1 JUN 2012		92680LL	1 AUG 2012		94625LL	1 OCT 2012
0409-1918-33 Preservative-Free 0.9% Sodium Chloride Inj., USP, 3 mL in 5 mL Carpuject™, Luer Lock								
	90755LL	1 JUN 2012		90805LL	1 JUN 2012			
0409-1918-35 Preservative-Free 0.9% Sodium Chloride Inj., USP, 5 mL in 5 mL Carpuject™, Luer Lock								
	91585LL	1 JUL 2012		94670LL	1 OCT 2012			
0409-2306-12 Preservative-Free Midazolam Inj., USP, 1 mg/mL, 2 mL in 2.5 mL Cartridge, iSecure™ V2								
	91710LL	1 JUL 2012		02500LL	1 FEB 2013		04570LL	1 APR 2013
	13700LL	1 JAN 2014						

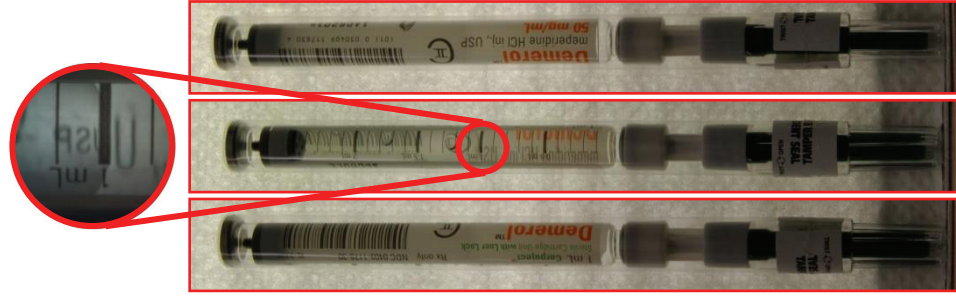
NDC / PRODUCT	LOT	EXP		LOT	EXP		LOT	EXP
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0409-2306-62 Preservative-Free Midazolam Inj., USP, 1 mg/mL, 2 mL in 2.5 mL Carpuject™								
	91570LL	1 JUL 2012		94500LL	1 OCT 2012		95630LL	1 NOV 2012
	04630LL	1 APR 2013		13685LL	1 JAN 2014		13690LL	1 JAN 2014
0409-1782-69 Naloxone HCL Inj., USP 0.4 mg/mL, 1 mL in 2.5 mL Carpuject™, Luer Lock								
	94780LL	1 OCT 2012		08655LL	1 AUG 2013			
0409-1120-12 Ondansetron Injection, USP, 2 mg/mL, 2 mL in 2.5 mL Cartridge, iSecure™ V2								
	07695LL	1 JUL 2013		07700LL	1 JUL 2013		07705LL	1 JUL 2013
	10760LL	1 OCT 2013		13525LL	1 JAN 2014			

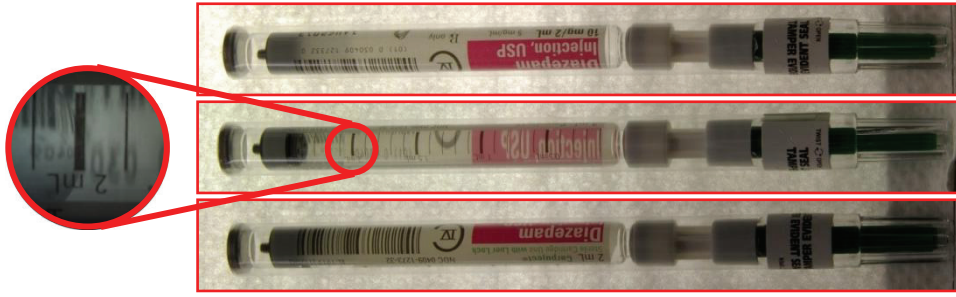
Examples of correct Carpuject™ fill volumes



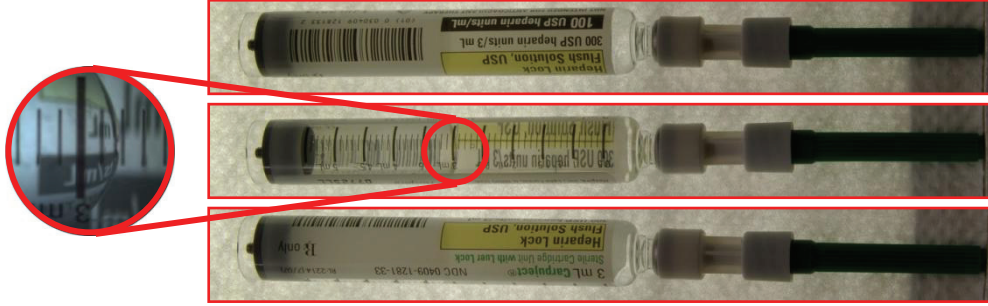
0.5 mL in 2.5 mL
Carpuject™



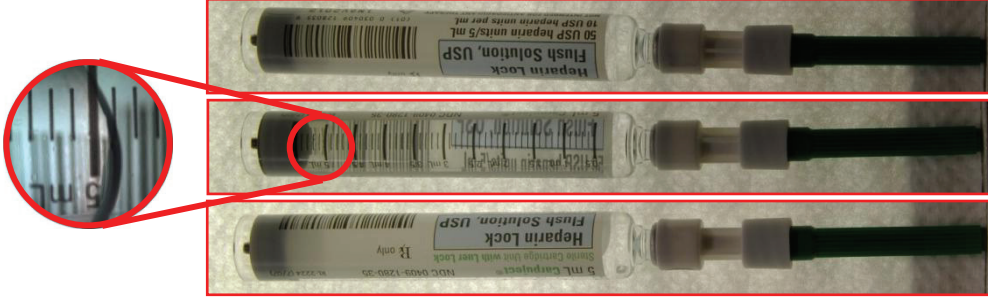
1 mL in 2.5 mL
Carpuject™



2 mL in 2.5 mL
Carpuject™



3 mL in 5 mL
Carpuject™



5 mL in 5 mL
Carpuject™