

Hemo-Stat Solution / Axcentria Pharmaceuticals, LLC. RECALL (8/14)

Reason/Information:

Axcentria Pharmaceuticals issued a recall on the following materiel. Reason: Marketed without an approved New Drug Application / Abbreviated New Drug Application (NDA/ANDA). Product is being manufactured and distributed without a NDC number.

Hemo-Stat Solution is Aluminum chloride 25%, in 37.2 g glass bottles most often used for dental procedures.

Disposition/Instructions:

Check inventory. If the customer has the affected product, quarantine and call Axcentria at 215-453-5055 or email at custserv@axcentria.com for further guidance.

Item Information:

NSN (FSC-NIIN): 6520-012536846
Nomenclature: HEMO-STAT SOLUTION, ALUMINUM CHLORIDE 25%, IN 37.2 G
GLASS BOTTLES
UI: BO
Manufacturer: AXCENTRIA PHARMACEUTICALS, LLC
Distributor: Benco Dental, Henry Shein

LOT / SN:
D13076 G12069 G13120 H12087
H12089 I13145 J13165 J13166
L12161

NOTES:

NOTE 1:

"This product is NOT a direct match with the above listed NSN, however, the Medical Master Catalog indicates that it may be associated."

NSN (FSC-NIIN): 6520-NS1
Nomenclature: HEMO-STAT SOLUTION, ALUMINUM CHLORIDE 25%, IN 37.2 G
GLASS BOTTLES
UI: BO
Manufacturer: AXCENTRIA PHARMACEUTICALS, LLC
Distributor: Benco Dental, Henry Shein

LOT / SN:
D13076 G12069 G13120 H12087
H12089 I13145 J13165 J13166
L12161

NOTES:

NOTE 1:

Lot #G12069 - Expiration Date - July 2014; Lot #H12087 - Expiration Date - August 2014;
Lot #H12089 - Expiration Date - August 2014; Lot #L12161 - Expiration Date - December 2014;
Lot #D13076 - Expiration Date - April 2015; Lot #G13120 - Expiration Date - July 2015; Lot
#I13145 - Expiration Date - September 2015; Lot #J13165 - Expiration Date - October 2015; Lot
#J13166 - Expiration Date - October 2015

POC Contact Information:

USAMMC-E

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Additional Message Recipients:

Please ensure widest dissemination of information to all interested entities.

Message Dissemination Authorization:

US AIR FORCE

AF Activities Will Take Action As Prescribed In AFI 41-209, Medical Logistics Support, Chapters 3 And 9. For MAJCOMS & NGB--This Msg Has Been Transmitted To All Designated Subordinate Medical Activities.

US ARMY

See Army Regulation (Ar) 40-61, 28 January 2005, Chapter 4, And The Department Of The Army Supply Bulletin (Sb 8-75-11) For Applicable Policies And Procedures.