

FROM
QUAD SERVICE MMQC FT DETRICK MD//USAMMA/AFMLO/NMLC//

PRIORITYMESSAGE RELEASED: 10/17/2012

*****UNCLASSIFIED*****

SUBJ: MMQC-12-1616
NEW ENGLAND COMPOUNDING CENTER (NECC) / TRIAMCINOLONE ACETONIDE / CARDIOPLEGIC
SOLUTION / ADDITIONAL PATIENT NOTIFICATION ADVISORY / FDA MEDWATCH / DLA 12-369A

REF: MMQC-12-1592

IMAGE ON USAMMA'S WEBSITE.

RECALL TO RETAIL LEVEL.

01. FDA ISSUED AN UPDATE ON FOL MATL ON 15 OCT 2012. REASON: AS A RESULT OF THE ONGOING INVESTIGATION OF NECC, A PATIENT W/POSSIBLE MENINGITIS POTENTIALLY ASSOCIATED W/EPIDURAL INJ OF ADDITIONAL NECC PROD HAS BEEN IDENTIFIED. SEE PARA 03 FOR MORE INFO & (SEE IMAGE ON USAMMA'S WEBSITE).

DISP: COMPLY W/MFR DIST INSTRS. FOLLOW-UP W/PATIENTS WHO WERE ADMINISTERED ANY INJECTABLE MEDS FROM OR PRODUCED BY NECC, INCLUDING INJECTABLE OPHTHALMIC DRUGS USED IN CONJUNCTION W/EYE SURGERY, OR A CARDIOPLEGIC SOLUTION PURCHASED FROM OR PRODUCED BY NECC AFTER 21 MAY 12. SEE PARA 04 FOR MORE INFO. QUESTIONS, CALL 508-872-0044.

NSN: 6505-NS1 UI: EA
NOM: TRIAMCINOLONE ACETONIDE INJ
MFR: NECC
LOT/SERIAL NUMBER(S):
ALL

02. REASON AND DISPOSITION AS ABOVE.

NSN: 6505-NS2 UI: EA
NOM: CARDIOPLEGIC SOLUTION
MFR: NECC
LOT/SERIAL NUMBER(S):
ALL

03. TRIAMCINOLONE ACETONIDE IS A TYPE OF STEROID INJECTABLE PRODUCT MADE BY NECC. THE CASES OF MENINGITIS IDENTIFIED TO DATE HAVE BEEN ASSOCIATED WITH METHYLPREDNISOLONE ACETATE, ANOTHER SIMILAR STEROID INJECTABLE PRODUCT.
IN ADDITION, TWO TRANSPLANT PATIENTS WITH ASPERGILLUS FUMIGATUS INFECTION WHO WERE ADMINISTERED NECC CARDIOPLEGIC SOLUTION DURING SURGERY HAVE BEEN REPORTED.

INVESTIGATION OF THESE PATIENTS IS ONGOING; AND THERE MAY BE OTHER EXPLANATIONS FOR THEIR ASPERGILLUS INFECTION. CARDIOPLEGIC SOLUTION IS USED TO INDUCE CARDIAC MUSCLE PARALYSIS DURING OPEN HEART SURGERY TO PREVENT INJURY TO THE HEART.

04. HEALTHCARE PROFESSIONALS AND MEDICAL CARE ORGANIZATIONS SHOULD INFORM PATIENTS WHO RECEIVED THE NECC PRODUCTS NOTED ABOVE OF THE SYMPTOMS OF POSSIBLE INFECTION AND INSTRUCT PATIENTS TO CONTACT THEIR HEALTHCARE PROVIDER IMMEDIATELY IF THEY EXPERIENCE ANY OF THESE SYMPTOMS.

05. FDA ADVISES HEALTHCARE PROFESSIONALS AND PATIENTS TO REPORT ADVERSE EVENTS OR SIDE EFFECTS RELATED TO THE USE OF THESE PRODUCTS TO THE FDA'S MEDWATCH SAFETY INFORMATION AND ADVERSE EVENT REPORTING PROGRAM:

* COMPLETE AND SUBMIT THE REPORT ONLINE: [WWW.FDA.GOV/MEDWATCH/REPORT.HTM](http://www.fda.gov/Medwatch/report.htm)
[HTTP://WWW.FDA.GOV/MEDWATCH/REPORT.HTM?SOURCE=GOVDELIVERY](http://www.fda.gov/Medwatch/report.htm?source=GOVDELIVERY)

* DOWNLOAD FORM
[HTTP://WWW.FDA.GOV/SAFETY/MEDWATCH/HOWTOREPORT/DOWNLOADFORMS/DEFAULT.HTM?SOURCE=GOVDELIVERY](http://www.fda.gov/Safety/Medwatch/HowtoReport/DownloadForms/default.htm?source=GOVDELIVERY)

OR CALL 1-800-332-1088 TO REQUEST A REPORTING FORM, THEN COMPLETE AND RETURN TO THE ADDRESS ON THE PRE-ADDRESSED FORM, OR SUBMIT BY FAX TO 1-800-FDA-0178

HEALTHCARE PROFESSIONALS MAY DIAL FDA'S DRUG INFORMATION LINE AT 855-543-DRUG (3784) AND PRESS * TO GET THE MOST RECENT INFORMATION REGARDING THE MENINGITIS RECALL AND SPEAK DIRECTLY TO A PHARMACIST.

READ THE MEDWATCH ALERT, INCLUDING A LINK TO THE FDA STATEMENT, AT:

[HTTP://WWW.FDA.GOV/SAFETY/MEDWATCH/SAFETYINFORMATION/SAFETYALERTSFORHUMANMEDICALPRODUCTS/UCM323946.HTM](http://www.fda.gov/Safety/Medwatch/SafetyInformation/SafetyAlertsForHumanMedicinalProducts/UCM323946.htm)

06. PASS MSG TO MEDICAL LOG OFCRS, CMD CHANNELS, PHARMACY, RISK MANAGERS, PAIN MEDICINE, MED STAFF, SUPPLY OFCRS, AND SUPPORTED ACTYS/CTRS.

07. AUTHORITY: DODD 5105.22 AND DODD 6025.13. ADDITIONALLY:

A. 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.

B. 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.

08. SERVICE SPECIFIC POCS ARE AS FOLS (FAX NOS. ARE AVAILABLE 24 HRS);
ARMY: TELEPHONE COM: 301-619-4320, DSN: 343, FAX: 4468,
E-MAIL: QUADSERVICEMMQC@AMEDD.ARMY.MIL

ARMY MEMBERS MAY SUBSCRIBE TO DOD MMQC MESSAGES AND MANY OTHER TOPICS AT THE FOLLOWING WEBSITE:

[HTTP://WWW.USAMMA.ARMY.MIL/ASSETS/APPS/NALA_QAWEB/NALA_INDEX.CFM](http://www.usamma.army.mil/assets/apps/nala_qaweb/nala_index.cfm)

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USAMMC-E: TELEPHONE COM: 011-49-6331-86-7118/7181, DSN: 495-7118, FAX: 6218,

E-MAIL: USAMMCE_QA@AMEDD.ARMY.MIL

AIR FORCE: TELEPHONE COM: 301-619-4170, DSN: 343, FAX: 2557

EMAIL: AFMOA.SGALC@DETRICK.AF.MIL

AIR FORCE MEMBERS MAY SUBSCRIBE TO THE DOD MMQC MESSAGES AND RECEIVE EMAIL NOTIFICATIONS DIRECTLY FROM USAMMA WHEN THEY ARE PUBLISHED AT THE FOLLOWING WEBSITE: [HTTPS://MEDLOG.DETRICK.AF.MIL/](https://medlog.detrick.af.mil/), GO TO "SITE SETTINGS" AND CHECK "SUBSCRIBE TO MMQC MESSAGES."

NAVY: TELEPHONE COM: 301-619-3085, DSN: 343, FAX: 2473,

EMAIL: MMQC2@MED.NAVY.MIL

NAVY MEMBERS MAY SUBSCRIBE TO RECEIVE DODMMQC MESSAGES AT

[HTTP://WWW.USAMMA.ARMY.MIL](http://www.usamma.army.mil) CLICK ON "SUBSCRIBE TO MMQC MESSAGES."