الرقم المحفوظات: 0356
رقم الصادر: 08/10/2011
بيروت، في: 06 أيار 2011

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي معروض.

الجهاز المعنى بالمتابعة:
- Bone Substitude, ACTIFUSE ABX, Actifuse MIS
Trade Mark: Baxter Healthcare
Local Representative:

بناءً على التقارير الصادرة عن الوكالة البريطانية
Medicine and Health Care Products Regulatory Agency (UK) MHRA
والنصوص الصادرة عن الشركة المصنعة والتي تفيد بوجود مضاعفات ناتجة عن استعمال
المادة المذكورة أعلاه، نرجو منكم تعميم هذه النشرة على المستشفيات المعنية.

رفق ربط:
- التوصية الصادرة عن الشركة المصنعة.

يبلغ:
- دائرة البرامج والمشاريع
- الموقع الإلكتروني لوزارة الصحة
- المحفوظات

مدير عام الصحة

[ลายو]
05th September, 2012

Subject: Use of ACTIFUSE ABX and ACTIFUSE MIS Synthetic Bone Substitute in Pediatric Patients with Large Bone Cysts

Products Concerned: Actifuse ABX and Actifuse MIS Synthetic Bone Substitute

Product Codes Concerned: 506005078048, 506005078049, 506005078057, 506005078059, 506005078069, 506005078071

Dear Theatre Manager / Surgeon,

Baxter is providing you with important product information regarding ACTIFUSE ABX and ACTIFUSE MIS Synthetic Bone Substitute.

This product communication is being provided as a result of isolated reports of postoperative fever and inflammatory reactions (in the absence of bacterial infection) with use of Actifuse ABX in paediatric patients undergoing surgical removal of large juvenile bone cysts. The reported side effects had no negative impact on therapeutic outcome or function of the ACTIFUSE ABX product.

While this patient group represents a small and highly select population of ACTIFUSE ABX patients, a causal relationship cannot be confirmed but can also not be fully excluded. A precautionary statement will be added to the ACTIFUSE ABX and ACTIFUSE MIS Instructions for Use as follows:

“Actifuse should be used with caution in paediatric cases harboring large Juvenile Bone Cysts. Isolated cases of transient postoperative fever and inflammatory reaction, in the absence of infection have been reported from clinical experience with extremely large cysts. This side effect had no impact on the therapeutic outcome.”

Please note that you are not being asked to return any product. You can continue to use ACTIFUSE ABX and ACTIFUSE MIS according to the Instructions for use and this important product information.

If you provide this product to other services/facilities/departments, please forward this information as appropriate to ensure correct ACTIFUSE ABX and ACTIFUSE MIS utilization in your institution.

This important product information is being sent by mail with return receipt. The return receipt serves as confirmation of receipt for our documentation. The Medicines and Healthcare Regulatory Authority has been informed about this action.
If you have any questions please contact Baxter at Surecall Baxter Medical Information on 01635 206345 or surecall@baxter.com.

Sincerely,

[Signature]

Richard Coghill
Business Unit Manager BioSurgery, Baxter Healthcare