



رقم المحفوظات: ١٣١/١٤٤٥٩
رقم الصادر: ١٣١/١٤٤٥٩
بيروت، في: ٢٤ نيسان ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة مستحضر طبي

Sterile Water for irrigation for Irrigation Pour Bottle

الجهاز المعنى بالمتابعة:

- Sterile Water for irrigation for Irrigation Pour Bottle
- Trade Mark: Baxter Corp Canada
- Local Representative:

بناء على التقرير الصادر عن الشركة المصنعة والذي يشير الى احتمال تكون بعض الطفيليات في الصنف الوارد اعلاه ، مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة
- يبلغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار



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E-mail: ncmdr.md@sfd.gov.sa**

Subject: Sterile Water for irrigation for Irrigation Pour Bottle

Product code: UKF7114, Batch number 12H28B27

Dear Sirs,

Baxter is writing to inform you of an action requested by the French Authorities (ANSM), following a quality complaint from a French Hospital related to the presence of “non *Aspergillus* saprophyte filamentous fungus” (mould) found during routine contamination control testing of a sample of Sterile Water for Irrigation Pour Bottle (code UKF7114) batch 12H28B27; Batch number 12H28B27 was distributed in France, UK, Ireland and Portugal.

Baxter immediately initiated a comprehensive and systematic investigation which thus far has provided a preponderance of evidence that the test contamination observed by the customer did not originate from the manufacturing process.

The ANSM have requested Baxter to notify customers in France and recommend the product to be quarantined at customer level while the investigation proceeds. Baxter has distributed such a communication, approved by ANSM, to all impacted customers in France.

While the investigation is in progress, Baxter has quarantined the remaining inventory of batch 12H28B27 at warehouse level.

On 7th February 2013, Baxter received a second notification from this French customer, informing us that, during subsequent testing on units from batch 12H28B27, performed after the initial report, positive results for mould were only observed when swabs were taken from the external surfaces of the pour bottle and negative results for mould were observed when the solution itself was tested. This latest update further supports Baxter's

شركة باكستر آيه جي. المكتب العلمي س.ت: ١٠١٠٢٠٦٥٦٦ هاتف ٢٩١٤٣٤٨ (٩٦٦١). فاكس ٢٩١٤٢٣٨ (٩٦٦١)
ص.ب. ٢٤٦٩٦٨ الرياض ١١٣١٢ - المملكة العربية السعودية

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finding to date i.e. there is a preponderance of evidence that the test contamination observed by the customer did not originate from the manufacturing process.

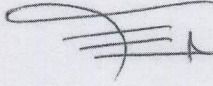
Baxter does not intend to take any immediate field action in UK, Ireland and Portugal at this time, pending full investigation. This is based on detailed internal investigation and results to date.

Baxter will continue the investigation, including sterility and bioburden testing on returned samples which are currently in incubation with expected results by 15th February 2013.

Please contact me should you need more clarifications.

Sincerely,

Abdulilah AlMalik



Scientific Officer Director

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شركة باكتيرأيه جي. المكتب العلمي س.ن.ت: ١٠١٠٢٠٦٥٦٦ هاتف ٢٩١٤٣٤٨ (٩٦٦١) فاكس ٢٩١٤٢٣٨ (٩٦٦١)

ص.ب. ٢٤٦٩٦٨ الرياض ١١٣١٢ - المملكة العربية السعودية

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