Bristol-Myers Squibb Pharmaceuticals
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Direct Healthcare Professional Communication - Recall of Questran 4g/sachet Powder for Oral Suspension, PA0048/020/001

6th June 2013

Dear Doctor,

Summary

This letter is to inform you that Bristol-Myers Squibb (BMS) is recalling, as a precautionary measure, all in-date batches of Questran 4g/sachet Powder for Oral Suspension (cholestyramine resin) ['Questran'] to pharmacy level with immediate effect.

Details

- Questran is being recalled due to possible contamination with *Enterococcus faecium*. The source of the possible contamination is believed to be the sucrose used in Questran. To date the presence of *Enterococcus faecium* has not been detected in commercial batches of Questran and there have been no product complaints or reported adverse health events in connection with this issue.
- This recall is going to pharmacy level. This action has been agreed with the Irish Medicines Board (IMB).
- BMS foresees a shortage of Questran because of this issue and you are kindly asked to use alternative treatments.

Adverse reaction reporting

Suspected adverse reactions should be reported to the IMB using a Yellow Card obtained either from the IMB, or electronically via the website at www.imb.ie. Adverse reactions can also be reported to the IMB by calling 01-6764971.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Any suspected adverse reactions for Questran may also be reported to Bristol-Myers Squibb via telephone at 1 800 749 749 or via email at medical.information@bms.com.

Further information

Should you have any further questions, including queries about alternative treatments, please contact Bristol-Myers Squibb Medical Information at 1800 749 749 or via email at medical.information@bms.com.

We apologise for any inconvenience that this action may cause.

Yours sincerely,

Siobhan Mitchell

Dr Siobhan Mitchell
Medical Director, Bristol-Myers Squibb Pharmaceuticals

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