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Dear Healthcare Professional Communication

Lucentis® 10mg/ml solution for injection
EU/1/06/374/001
Lot Numbers S0048 and S0051

18 February 2011

Presence of blocked needles in some Lucentis® injection administration packs

Dear Healthcare Professional,

Following discussion with the European Medicines Agency and the Irish Medicines Board, we wish to advise you of the following:

Summary

- Novartis Pharma has received a number of technical complaints regarding the injection administration packs of Lucentis® 10mg/ml solution for injection (ranibizumab).
- These complaints relate to cases of blocked injection needles which were identified during the preparation of the injection (priming, while expelling air from the needle).
- Three cases of bacterial endophthalmitis have been reported for batches with a higher rate of blocked needle complaints and since the role of the blocked needles in these adverse events cannot be ruled out, the following recommendations are given:

1. Please **do not use** the **injection needle*** (the yellow needle) contained in the Lucentis® injection administration packs with **lot numbers: S0048 and S0051.**
2. Please discard this yellow needle in these lots and instead, use another 30-gauge (0.3X13mm) needle* for ophthalmic injection available in your hospital or clinic.
3. You can continue to use the Lucentis vial.
4. As usual, the injection procedure has to be carried out under aseptic conditions

This communication has been agreed with the Irish Medicines Board.

Further information

A higher rate of blocked needles was observed since October 2010. The number of reports received varies by country from less than 1 in a 1000 to around 1 in a 100 packs administered. For the Lucentis batches for which a higher rate of blocked needle complaints was observed, three cases of bacterial endophthalmitis were reported in association with complaints of blocked needles. Endophthalmitis is an inflammatory or infectious condition of the intraocular cavities of the eye caused by an external contaminant. Although the risk of contamination associated with replacing needles is very low, there is a temporal association of these cases with the occurrence of blocked needles. Therefore, the role of the additional handling procedures required to substitute the defective needle cannot be excluded.

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This quality defect issue concerns the Becton Dickinson needle lot numbers 100224 and 100609(*), contained in Lucentis® injection administration packs which were manufactured between mid-August 2010 and January 2011. The corresponding batches of Lucentis® administration packs have the following **lot numbers: S0048 and S0051**. The complaints are confined to the injection needles only and not to the Lucentis® vial. There is no need to stop using Lucentis® as a result of this identified injection needle issue.

It has been confirmed that the components within the Lucentis® injection administration packs are sterile including the injection needle and the vials. However, it is theoretically possible that the additional manipulation caused by a blocked needle, such as a needle replacement, could increase the likelihood of non-sterility and possibly increases the risk of eye infection. Thus, the yellow needles in these packs should not be used and they should be discarded.

Novartis will make available new Lucentis injection administration packs with new needles as soon as possible, however, in the interim you may still receive packs from the above mentioned lot numbers. Please be assured that all actions are being taken to minimize interruption to the supply of Lucentis during this period.

As per usual practice, please continue the safety reporting related to the use of the product in accordance with local regulations to Novartis Drug Safety at 01-2601255 or to the Pharmacovigilance Section of the Irish Medicines Board (www.imb.ie). In particular, please report any cases suggestive of bacterial endophthalmitis immediately to Novartis Drug Safety at 01-2601255, and please ensure that the lot number of the product associated with any such adverse events is also reported.

For additional questions regarding this issue, please call the local Novartis Medical Information Officer at 01-2601255.

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