IN USE PRODUCT SAFETY ASSESSMENT REPORT FOR NEOFEL XL (FELODIPINE)

### SUMMARY OF ASSESSMENT AND ITS FINDINGS

#### BACKGROUND

Neofel XL® (felodipine tablets) manufactured by Neolab were highlighted as high risk on a Safe Medication Bulletin produced by Quality Control North West on behalf of the NHS Pharmaceutical Quality Assurance Committee Procurement sub-committee. The bulletin highlighted that the brand name was over prominent (Neofel XL®) and the generic name appeared in small font only. It was felt that there was very poor differentiation between strengths in the range and this may lead to incorrect selection. Due to the potential safety concerns associated with the product packaging a decision was made in 2013 to award a NHS contract to the 2.5mg strength only. Subsequent to this decision, the manufactures has changed the presentation of the 5mg and 10mg strength. A further assessment to ascertain the current level of risk is therefore warranted.

#### DETAILS OF PRODUCT (S) ASSESSED

Using the validated product safety assessment tool, UKMi have analysed the appropriateness of the new product packaging, and whether the patient safety issues described above have been addressed. We have compared the presentation of three available strengths: Neofel XL® (felodipine) 2.5mg, 5mg, and 10mg prolonged release tablets manufactured by Neolab (MA Holder Fannin UK Ltd).

#### CONCLUSION FOLLOWING APPLICATION OF VALIDATED ASSESSMENT TOOL

The following points were raised after independent consideration of Neofel XL® products by 3 pharmacists:

- In relation to *product packaging and presentation*, critical information was not always presented in the clearest way. The following points were raised:
  - The brand name was deemed more prominent than the generic name on the packaging, and this may affect user recognition of the product. In particular, the brand is not always followed by the generic name on all sides of the packaging. This was particularly concerning since it could hinder correct product selection in pharmacy and clinical settings.
  - The font size used to highlight the critical information is considered to be very small.
  - There is now some use of colour to distinguish between the three different strengths of Neofel XL®, but it was felt that mechanisms to aid differentiation between the various strengths could be further improved.
  - It was felt that the corporate livery for this product in particular (more so than other manufacturers) could have an effect on differentiation between other medicines manufactured by Neolab.
- Some negative language was also found in the accompanying *product literature*; for example: "Do not store your tablets above 25°C", "tablets should not be chewed or crushed". In the patient information leaflet accompanying the product, the medicine is mainly referred to as the brand name rather than generic name which could potentially lead to confusion.

In conclusion, in our view the current product packaging of Neofel XL® continues to present potential for confusion between different strengths. And the lack of emphasis of the generic name, in contrast to the brand name, could also contribute to confusion with other medicines (in particular perhaps those with look-alike names). Similarly (although not specifically assessed by this process), it is possible that the corporate livery could affect on differentiation between other medicines manufactured by Neolab. It should be noted that a range of other M/R felodipine products are available in the UK which may have clearer product packaging and labelling information (although at the time of writing none of these had been formally assessed).
POTENTIAL NEXT STEPS AND MITIGATION ACTIONS

Whilst there have undoubtedly been improvement since the Safe Medication Bulletin, our assessment suggests that action continues to be necessary to enable safe use of these products.

We recommend that the manufacturer and the NHS consider the following actions:

i. Manufacturer:
   - There should be more emphasis on the generic medicine name on the packaging of all faces.
   - Further judicious use of colour and other mechanisms to differentiate between strengths should be considered.
   - Improved labelling could highlight the difference between medicines with potentially look-alike names e.g. other calcium channel blockers.
   - The appropriateness of the corporate livery should be considered to enable the best possible differentiation between this and other Neolab products.

ii. NHS:
   Continue to consider purchasing arrangements that ensure different strengths of felodipine are available from different manufacturers, such that differentiation is ensured in pharmacy and clinical settings.

This report was produced in March 2014 using photographic images (not physical products) of Neofel XL® products available at the time of assessment. Images were obtained primarily from pharmaceutical companies, but also from various sources within the NHS.

This report summarises product assessments undertaken by:
London Medicines Information Service
North West Medicines Information Centre
Trent Medicines Information Centre

For comments email nwlh-tr.medinfo@nhs.net

IMAGES OF PRODUCTS