

1.3. PRODUCT INFORMATION

1.3.2 Mock-up

The Applicant would like to provide a justification regarding the proposed bottle label, in which it is not feasible to include all the necessary information.

According to the Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use (Rev.1, Jan 2009): “The particulars appearing on the label of all medicinal products should be printed in characters of at least 7 points (or of a size where the lower case "x" is at least 1.4 mm in height), leaving a space between lines of at least 3 mm. In particular the information presented on small packs will need careful consideration so that the text is presented in as large a type size as possible to reduce the likelihood of medication error.” According to the proposed mock-ups of inner labelling, the text size on bottle label will have to be smaller than recommended in the guideline, if complete bottle labelling is provided. This will increase the likelihood of medication error and, most importantly, it will be very difficult to be read by people with impaired eye sight to whom the product is intended. Consequently, the Applicant has decided to exclude some information from the bottle label.