1.3 Product Information

1.3.6 Braille

In accordance with Article 56a of Directive 2001/83/EC as amended and in line with the “Guidance concerning the Braille requirements for labelling and package leaflet” (ENTR/F2 DE (2005)) the nationally approved name of the medicinal product applied for will be expressed in Braille format on the outer/secondary packaging material intended for sale after finalisation of the DC procedures, if applicable.