Labelling

Official national and regional labelling requirements should be met.

When the term 'label' is used in the International pharmacopoeia, the labeling statements may appear on the container, the package or a leaflet accompanying the package, as decided by the relevant authority.

For dosage forms, the label should state whether an antimicrobial preservative has been added, its name and concentration, as well as those of other substances such as buffers and colouring agents.

Further indications should be given, such as the special route of administration of a dosage form and, whenever relevant, the shelf-life.