BULGARIA

Price

There is no requirement for the price to appear on the label.

Reimbursement

There is no requirement for the reimbursement conditions to appear on the label. Samples intended to be provided free of charge shall be labelled: Безплатна мостра

Legal Status

The requirements with respect to legal status are as follows:

- For medicinal products not subject to medical prescription, the following expression should appear: Без лекарско предписание
- For medicinal products subject to medical prescription, the following expression should appear: По лекарско предписание
- For medicinal products subject to restricted medical prescription, the following expression should appear:

По ограничено лекарско предписание

- For medicinal products reserved for treatments which can only be followed in a hospital environment due to limited experience or in the interests of public health, the following expression should appear:
 За болнична употреба
- For pack size/sizes which is/are not intended to be delivered to a particular patient but used in a hospital environment for several patients or several treatment courses of one patient, the following expression should appear: Болнична опаковка
- For medicinal products subject to special medical prescription, the following expression should appear:

По специално лекарско предписание, and

- 1. a double red line positioned diagonally on the package labels for medicinal products containing narcotic substances,
- 2. a double blue line positioned diagonally on the package labels for medicinal products containing psychotropic substances.

Identification and authenticity

The EAN code (bar code) is accepted but not required on the label.

Symbols or pictograms

Symbols for separate disposal and recycling in compliance with the Law on Waste Management are required on the outer packaging label of a medicinal product.

The labelling may include symbols or pictograms as well as other information consistent with the Summary of Product Characteristics and useful for the patient, excluding any element of advertising.

Invented name

Invented name written in Bulgarian language to appear on the outer packaging in blue box.

International nonproprietary name (INN) or common name INN or common name written in English language to appear on the outer packaging in blue box.