INFORMATION INCLUDED IN THE OUTER PACKAGING OF MEDICINES
General recommendations on pack design

*For the national phase of Mutual-recognition / Decentralised procedures, mock-ups should be submitted in Spanish.

The shaded areas < > represent data that can vary depending on the type of the medicine.

Critical information on the front panel:

- Invented name or INN + Strength + Pharmaceutical form (should appear as a visual unit; all information should be included in a homogeneous font size).

- Acronyms EFG: only generics medicines.

- Active substance(s): will be included when it is not part of the invented name or when it is a specific salt of the active substance.

- Total amount inclusion: when relevant for the correct administration, e.g. total amount of active substance per total volume in parenteral preparations.

- Route(s) of administration: according to Standard Terms.

- Contents of pack size (pictograms of the actual pharmaceutical form may be included).

- Pharmaceutical form: according to Standard Terms.

- Therapeutic indication and target group (only for non-prescription medicines).

- National product number + symbols + acronyms: upper right corner.

- Name in braille alphabet: except for medicines administered by healthcare professionals.

OTHER SYMBOLS

SIGRE SYMBOL
(Except hospital use)

▶ For more information

DRIVING PICTOGRAM:

▶ For more information

Conducción: ver prospecto

Packaging mock-up labels

<General classification for supply>

Conducción - ver prospecto

XXXXXXX <symbols & acronyms>

Name + Strength + Pharmaceutical form <+ EFG>
Active substance(s)

Route(s) of administration
Contents of pack size

PC 0030597010 0614
SN : 1234567890 1234
Lote 123456
EXP 12 2020

Anti-tampering device

Barcode

Read the package leaflet before use
Keep out of the sight and reach of children

Box or blank for posology

Name and address of the MAH
Local representative

XXXXXXX <symbols & acronyms>

Name + Strength + Pharmaceutical form <+ EFG>
Active substance(s)

Each tablet contains XX mg of active substance(s) <also contains <excipient(s) with known effect and other excipients>. See the package leaflet for further information>

<Special storage conditions>

Route(s) of administration
Contents of pack size

Route(s) of administration
Contents of pack size

Name + Strength + Pharmaceutical form <+ EFG>
Active substance(s)

Anti-tampering device

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

SYMBOLS AND ACRONYMS:

○ Dispensing subjected to medical prescription.

◑ Medicines containing psychotropic substances included in annex I of RD 2829/1977, of October 6, 1997.

● Drugs subjected to official prescription for narcotic drugs in Schedule I annexed to the 1961 Single Convention.

◐ Medicines containing psychotropic substances included in Annex II of RD 2829/1977, of October 6, 1977.

✳ Storage in a refrigerator (2°C – 8°C).

XXXXXX.X National product number (national requirement).

DH Diagnóstico hospitalario.

H Uso hospitalario.

MTP Medicamento tradicional a base de plantas.

TLD Tratamiento de larga duración (only applicable to active substances already qualified as such and their generics).

GENERAL CLASSIFICATION FOR SUPPLY

⊙ **MEDICAMENTO SUJETO A PRESCRIPCIÓN MÉDICA** → Medical product subjected to medical prescription

⊙ Medicamento no sujeto a prescripción médica → Medicinal product not subjected to medical prescription

⊙ Uso hospitalario → For medicinal products classified as hospital use

⊙ Diagnóstico hospitalario → For medicinal products classified as hospital diagnostic drugs

SAFETY FEATURES

UNIQUE IDENTIFIER – 2D BARCODE

PC
SN

Lote
CAD

▶ **For more information**

ANTI-TAMPERING DEVICE

Anti-tampering device

▶ **For more information**

▶ **For more information about pack design**

Mock-ups are part of the MA of the medicinal product and should comply with current legislation, which indicates what information (text) is mandatory on the labelling. Recommendations on the general pack design and layout should be fulfilled (type size and font, print color and background), as well as the graphic elements (logos, drawings, symbols, etc.), to meet the readability requirements in mock-ups. Thus, dispensing and medication errors are avoided. For the national phase of the procedure, mock-ups should be submitted in Spanish.
For further information, please review: RD 1345/2007; RD 717/2019; QRD template and European Guideline on the readability of the labelling and package leaflet of medicinal products.