

2022 - X.XXX.X

Appendix 2 Bar code requirements

Secondary packaging – regulatory requirements¹

For pharmaceuticals produced on or before 8 February 2019, it is a requirement that the secondary packaging is marked with either EAN 13- bar code or 2D (GS1 DataMatrix) bar code containing as a minimum an NTIN or a GTIN.

For pharmaceuticals produced on or after 9 February 2019, it is a requirement that the secondary packaging is marked with 2D (GS1 DataMatrix) bar code containing GTIN, expiry date, batch/lot number and serial number.

Primary packaging – Amgros requirements

For all pharmaceuticals for oral use, all pharmaceuticals for external use as well as all pharmaceuticals for injection and for infusion, it is a requirement that the primary packaging is marked with a bar code. However, this requirement shall not apply to tablets or capsules in blister sheets or other similar packaging in which tablets/capsules are single dosed individually.

The bar code must either be an EAN 13 bar code or 2D (GS1 DataMatrix) bar code and must as a minimum contain an NTIN or a GTIN.

Pharmaceuticals for oral use means:

- Tablets or capsules
- Oral fluids and drops

Pharmaceuticals for external use means:

- Ointments, creams or gel

¹ Section on "Secondary packaging" is only a service information to Supplier and does not constitute a full list of requirements, permitted omissions etc. set out by the legislation. Therefore, Amgros assumes no responsibility for errors or omissions in the contents on the information. The Supplier is still responsible for complying with all regulatory requirements for the Pharmaceuticals.

- Cutaneous liquids

Pharmaceuticals for injection means:

- Injection fluid
- Concentrate for injection fluid
- Powder for injection
- Injection fluid in pre-filled syringe

Pharmaceuticals for infusion means:

- Infusion fluid
- Concentrate for infusion fluid
- Powder for infusion fluid

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EXAMPLE