

LABELLING

MINIMUM PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Vial carton: [BT-ON013 trade name]

- 1. Name of the medicinal product**
[BT-ON013 trade name]* Trastuzumab 150 mg powder for concentrate for solution for infusion
- 2. List of excipients**
Contains D-sorbital
See patient information leaflet for further information.
- 3. Pharmaceutical form and contents**
Lyophilized powder for concentrate for solution for infusion
1 vial
- 4. Method and route of administration**
For intravenous use.
Read the patient information leaflet before use.
- 5. Special warning that the medicinal product must be stored out of the reach and sight of children**
Keep out of the reach of children.
- 6. Other special warning(s), if necessary**
- 7. Expiry date**
EXP {MM/YYYY}
- 8. Special storage conditions**
Store at 2°C-8°C, in the original package in order to protect from light.
The reconstituted solution should be used immediately.
- 9. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**
- 10. Name and address of the supplier**
Biocon Biologics Limited
16 Great Queen Street
Covent Garden, London
United Kingdom
WC2B 5AH
- 11. WHO Reference Number (Prequalification Programme)**
BT-ON013

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

12. Manufacturer's batch number

<Batch> <Lot> {number}

13. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

14. Instructions on use

For intravenous use after reconstitution with sterile water for injection and further dilution with 0.9% sodium chloride injection.

Single use vial. Discard unused portions.

Reconstituted and further diluted solutions that show discoloration, haziness, visible particulate matter or precipitation should not be used.

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Vial

1. Name of the medicinal product

[BT-ON013 trade name] Trastuzumab 150 mg lyophilized powder for concentrate for solution for infusion

2. List of excipients

Contains D-sorbitol

3. Method and route of administration

For intravenous use.

Read the patient information leaflet before use.

4. Expiry date

EXP {MM/YYYY}

5. Special storage conditions

Store at 2°C-8°C, in the original package in order to protect from light.

6. Name and address of the supplier

Biocon Biologics Limited

7. Manufacturer's batch number

<Batch> <Lot> {number}

8. (Advice on) General classification for supply

Medicinal product subject to medical prescription.