

LABELLING

MINIMUM PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Vial carton

1. Name of the medicinal product

[BT-ON014 trade name]* Trastuzumab 420 mg powder for concentrate for solution for infusion
Co-packed with Bacteriostatic Water for Injection

2. List of excipients

[BT-ON014 trade name]
Contains D-sorbitol

Bacteriostatic water for injection
Contains benzyl alcohol 1.1% w/v

See patient information leaflet for further information.

3. Pharmaceutical form and contents

Lyophilized powder for concentrate for solution for infusion
1 vial

Bacteriostatic Water for Injection 20 mL
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.
Use reconstituted solution within 28 days when stored at 2°C-8°C

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

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

Covent Garden, London
United Kingdom
WC2B 5AH

11. WHO Reference Number (Prequalification Programme)

BT-ON014

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.

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: [BT-ON014 trade name]

1. Name of the medicinal product

[BT-ON014 trade name] Trastuzumab 420 mg lyophilized powder for concentrate for solution for infusion

2. List of excipients

Contains D-sorbital

See patient information leaflet for further information.

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

Multi-use vial.

Store at 2°C-8°C.

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.

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Vial: Diluent

- 1. Name of the product**
Bacteriostatic Water for Injection
- 2. Contents by volume**
20 mL
- 3. List of excipients**
Contains benzyl alcohol 1.1% w/v
See patient information leaflet for further information.
- 4. Method of administration**
For drug diluent use only.
Read the patient information leaflet before use.
- 5. Expiry date**
EXP {MM/YYYY}
- 6. Special storage conditions**
Store at 2°C-8°C
- 7. Name and address of the supplier**
Biocon Biologics Limited
- 8. Manufacturer's batch number**
<Batch> <Lot> {number}
- 9. (Advice on) General classification for supply**
Medicinal product subject to medical prescription.