

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[NT020 trade name]* Azithromycin (as dihydrate) 500 mg film-coated tablets
Azithromycin

2. Statement of active substance

Each film-coated tablet contains 500 mg of azithromycin (as dihydrate)

3. List of excipients

Contains lactose monohydrate

4. Pharmaceutical form and contents

Film-coated tablets
10 x 3 tablets

5. Method and route of administration

Oral use.
Read the patient information leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep this medicine out of the sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C. Avoid excursions above 30°C. Protect from light and moisture.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

11. Name and address of the supplier

Rusan Pharma Ltd.

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

58-D, Government Industrial Estate,
Charkop, Kandivali (West),
Mumbai - 400 067
Maharashtra. India

12. WHO Reference Number (Prequalification Programme)

NT020

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

PVC/PVDC-Alu foil blister cards

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Azithromycin

2. Name of the supplier

Rusan Pharma Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other