LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1.   Name of the medicinal product

[HA595 trade name]* Ondansetron (as hydrochloride dihydrate) 4 mg tablets

Ondansetron hydrochloride dihydrate

2.   Statement of active substance

Each film-coated tablet contains 4 mg ondansetron hydrochloride dihydrate

3.   List of excipients

Each film-coated tablet contains about 91 mg of lactose monohydrate

See patient information leaflet for further information

4.   Pharmaceutical form and contents

Film-coated tablets

1x10 tablets

2x10 tablets

3x10 tablets

5x10 tablets

6x10 tablets

9x10 tablets

10x10 tablets

30x10 tablets

1x30 tablets

2x30 tablets

3x30 tablets

10x30 tablets

5.   Method and route of administration

Oral use.

Do not chew.

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.

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

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30ºC. Protect from light.

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

Cadila Pharmaceuticals Limited

1389, Trasad Road

Dholka Ahmedabad

Gujarat 382 225,

India

12. WHO Reference Number (Prequalification Programme)

HA595

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
Blister

1. **Name of the medicinal product**

   [HA595 trade name] Ondansetron (as hydrochloride dihydrate) 4 mg tablets

   Ondansetron hydrochloride dihydrate

2. **Name of the supplier**

   Cadila Pharmaceuticals Limited

3. **Expiry date**

   EXP {MM/YYYY}

4. **Manufacturer's batch number**

   <Batch> <Lot>{number}

5. **Other**