

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[HA515 trade name]¹ Ganciclovir 500 mg (as ganciclovir sodium)
Ganciclovir (as sodium)

2. Statement of active substance

Each vial contains 500 mg of ganciclovir (as ganciclovir sodium).

3. List of excipients

Each vial contains 43 mg sodium.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Powder for concentrate for solution for infusion (powder for concentrate).

Each carton contains 10 vials.

5. Method and route of administration

For intravenous use after reconstitution and dilution.

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 out of the sight and reach of children.

7. Other special warning(s), if necessary

Avoid direct contact with or inhalation of the powder contained in the vial or direct contact of the solution with skin or mucous membranes.

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C. Store in the original container.

After reconstitution the product should be used within 12 hours. Do not refrigerate reconstituted solution.

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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

Hainan Poly Pharm. Co. Ltd.
Guilinyang Economic Development Area
Haikou,
Hainan Province, China
Tel:+ 86 898 6571 2762
Fax: + 86 898 6571 0298
Email: zm@hnpoly.com

12. WHO Reference Number (Prequalification Programme)

HA515

13. Manufacturer's batch number

<Batch> {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

Vial label

1. Name of the medicinal product

[HA515 trade name]² Ganciclovir 500 mg (as ganciclovir sodium)
Ganciclovir (as sodium)

2. Name of the supplier

Hainan Poly Pharm. Co. Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other

² Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.