

## **LABELING**

Ganciclovir (as sodium salt) 500 mg Powder  
for Injection (Hainan Poly Pharm Co Ltd),  
HA515

WHOPAR Part 5

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**CARTON (pack of 10 vials)**

**1. NAME OF THE MEDICINAL PRODUCT**

Ganciclovir 500 mg Powder for Infusion\*

**2. STATEMENT OF ACTIVE SUBSTANCE**

Ganciclovir 500 mg (as ganciclovir sodium).

**3. LIST OF EXCIPIENTS**

Each vial contains 46 mg sodium.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Each carton contains 10 vials of ganciclovir sodium equivalent to 500 mg ganciclovir.

**5. METHOD AND ROUTE OF ADMINISTRATION**

For injection  
Read the package 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 reach and sight of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

Irritant: handle with caution

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\*Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

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**8. EXPIRY DATE**

EXP {MM/YYYY}

**9. SPECIAL STORAGE CONDITIONS**

Do not store above 30°C.

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

**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.  
Meilan District  
Guilinyang Economic Development Area  
Haikou  
Hainan Province  
China  
Tel: + 86 898 65712762  
Fax: + 86 898 65710298  
Email: [minhuaf@hnpoly.com](mailto:minhuaf@hnpoly.com)

**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

HA515

**13. MANUFACTURER'S BATCH NUMBER**

&lt;Batch&gt; &lt;Lot&gt; &lt;BN&gt; {number}

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WHOPAR Part 5

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS**  
**Powder vial**

**1. NAME OF THE MEDICINAL PRODUCT**

Ganciclovir 500 mg Powder for Infusion

**2. NAME OF THE SUPPLIER**

Hainan Poly Pharm Co Ltd

**3. EXPIRY DATE**

EXP {MM/YYYY}

**4. BATCH NUMBER**

<Batch> <Lot> <BN> {number}