

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**{Carton Box}****1. NAME OF THE MEDICINAL PRODUCT**

Aciclovir Agila 25mg/ml Powder for Solution for Infusion

aciclovir

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One ml of the reconstituted solution for infusion contains 25mg Aciclovir sodium dihydrate

Each 10 ml vial contains aciclovir sodium dihydrate equivalent to 250 mg of aciclovir.

Each 20 ml vial contains aciclovir sodium dihydrate equivalent to 500 mg of aciclovir.

This medicinal product contains 24.5 mg sodium per dose

3. LIST OF EXCIPIENTS

None

Contains sodium. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Powder for solution for infusion

1 vial : 10 ml and 20 ml

5 vials: 10 ml and 20 ml

10vials: 10 ml and 20 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use as infusion after dilution

Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

For single use only,

8. EXPIRY DATE

EXP

After reconstitution, the product should be used immediately. Read the leaflet for further information.

9. SPECIAL STORAGE CONDITIONS**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

Discard any unused solution immediately after initial use.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Agila Specialties UK Limited, New bridge street House, 30-34 New Bridge Street, London EC4V 6BJ, United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE**16. INFORMATION IN BRAILLE**

Not applicable