LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR HDPE BOTTLE AND ALU/OPA/ALU/PVC BLISTER

1. NAME OF THE MEDICINAL PRODUCT

[Nationally completed name] 450 mg film-coated tablets

valganciclovir (as hydrochloride)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 450 mg of valganciclovir (as hydrochloride).

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Blister:
10 film-coated tablets
30 film-coated tablets
60 film-coated tablets
90 film-coated tablets
120 film-coated tablets

HDPE bottle:
60 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Oral 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

The film-coated tablets should not be broken or crushed.

8. EXPIRY DATE

EXP

Shelf life after first opening:
Bottles: 2 months

9. SPECIAL STORAGE CONDITIONS

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 MARKETING AUTHORISATION HOLDER

[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

[To be completed nationally]

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

[To be completed nationally]

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

LABEL FOR HDPE BOTTLE

1. NAME OF THE MEDICINAL PRODUCT

[Nationally completed name] 450 mg film-coated tablets

valganciclovir (as hydrochloride)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 450 mg of valganciclovir (as hydrochloride).

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

60 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Oral 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

The film-coated tablets should not be broken or crushed.

8. EXPIRY DATE

EXP

Shelf life after first opening:
2 months

9. SPECIAL STORAGE CONDITIONS

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 MARKETING AUTHORISATION HOLDER

[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

ALU/OPA/ALU/PVC BLISTER

1. NAME OF THE MEDICINAL PRODUCT

[Nationally completed name] 450 mg film-coated tablets

valganciclovir (as hydrochloride)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. OTHER