LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGING

HDPE Bottle

1. NAME OF THE MEDICINAL PRODUCT

Dolutegravir 50mg Tablets [1]

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 50 mg Dolutegravir (as sodium)

3. LIST OF EXCIPIENTS

See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

30 film-coated tablets
90 film -coated tablets

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use
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 reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP {MM/YYYY}

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

9. SPECIAL STORAGE CONDITIONS

Do not store above 30˚C.

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

Cipla Ltd.
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg
Lower Parel
Mumbai: 400013
India

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA 680

13. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE