

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

HDPE Bottle

1. NAME OF THE MEDICINAL PRODUCT

Isoniazid/Pyridoxine hydrochloride/Sulfamethoxazole/Trimethoprim
300 mg/25 mg/800 mg/160 mg Tablets *

2. STATEMENT OF ACTIVE SUBSTANCE

Each biconvex uncoated tablet contains:
Isoniazid 300 mg, Pyridoxine hydrochloride 25 mg, Sulfamethoxazole 800 mg, Trimethoprim
160 mg

3. LIST OF EXCIPIENTS

Tablets also contain sodium benzoate.

4. PHARMACEUTICAL FORM AND CONTENTS

30 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 sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Not applicable

* 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.

8. EXPIRY DATE

EXP {MM/YYYY}

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**

NA

11. NAME AND ADDRESS OF THE SUPPLIER

Cipla Ltd.
Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg
Lower Parel
Mumbai: 400 013
India.

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA639

13. MANUFACTURER'S BATCH NUMBER

B.No./ LOT No.

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE