LABELLING

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PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. NAME OF THE MEDICINAL PRODUCT

[MA131 trade name]*

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains 40 mg dihydroartemisinin and 320 mg piperaquine (as phosphate)

3. LIST OF EXCIPIENTS

See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Tablets

25 x 9 tablets
1 x 9 tablets
1x 6 tablets
2 x 6 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 this medicine out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

*Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Store in tightly closed containers, protected from light and moisture, not above 25°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

Guilin Pharmaceutical Co., Ltd
No. 43, Qilidian Road, Guilin 541004
Guangxi, China.

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

MA131

13. MANUFACTURER'S BATCH NUMBER

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

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

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MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE MEDICINAL PRODUCT

[MA131 trade name] †

2. NAME OF THE SUPPLIER

Guilin Pharmaceutical Co., Ltd

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

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

†Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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