

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label/Alu-Alu blister

1. NAME OF THE MEDICINAL PRODUCT

ARTECAP¹

2. STATEMENT OF ACTIVE SUBSTANCE

Each suppository contains 100 mg artesunate

3. LIST OF EXCIPIENTS

See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

1x2 suppositories

5. METHOD AND ROUTE OF ADMINISTRATION

Rectal
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}

¹Trade 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

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). Avoid excursions over 30°C. Do not freeze.

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

Strides Pharma Global Pte Limited
3, Tuas South Avenue 4
Singapore – 637610
Tel. No: + (65) 6708 8505
Fax No: + (65) 6708 8506

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

MA123

13. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.

15. INSTRUCTIONS ON USE

Read the patient information leaflet before use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

ARTECAP

2. NAME OF THE SUPPLIER

Strides Pharma Science Limited

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

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