

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Carton label/Alu-Alu blister**

**1. NAME OF THE MEDICINAL PRODUCT**

ARTECAP<sup>1</sup>

**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}

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<sup>1</sup>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**

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  
1 Gateway Drive  
#06-06  
Westgate Tower  
Singapore 608531

**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 Global Pte. Limited

**3. EXPIRY DATE**

EXP {MM/YYYY}

**4. BATCH NUMBER**

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