

## **LABELING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Blister Carton**

**1. NAME OF THE MEDICINAL PRODUCT**

[HA691 trade name]\*

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each tablet contains sulfamethoxazole 800mg and trimethoprim 160mg

**3. LIST OF EXCIPIENTS**

See patient information leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

10 x 10 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}

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

**9. SPECIAL STORAGE CONDITIONS**

Store at or below 30°C. Protect from light.

**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**

Milan Laboratories (India) Pvt Ltd  
303&304, Odyssey IT park  
Road No. 9, Opposite MIDC Office  
Wagle Estate  
Thane- Mumbai  
Maharashtra 400 604  
India

**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

HA691

**13. MANUFACTURER'S BATCH NUMBER**

<Batch> {number}

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**

**HDPE Bottle**

**1. NAME OF THE MEDICINAL PRODUCT**

[HA691 trade name]

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each tablet contains sulfamethoxazole 800mg and trimethoprim 160mg

**3. LIST OF EXCIPIENTS**

See patient information leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

500 tablets  
1000 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}

**9. SPECIAL STORAGE CONDITIONS**

Store at or below 30°C. Protect from light.

**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**

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**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

HA691

**13. MANUFACTURER'S BATCH NUMBER**

<Batch> {number}

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**MINIMUM PARTICULARS TO APPEAR ON BLISTER**

**1. NAME OF THE MEDICINAL PRODUCT**

[HA691 trade name]

**2. NAME OF THE SUPPLIER**

Milan Laboratories (India) Pvt Ltd

**3. EXPIRY DATE**

EXP {MM/YYYY}

**4. BATCH NUMBER**

<Batch> {number}