LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

Carton/bottle label(HDPE bottle)

1. NAME OF THE MEDICINAL PRODUCT

Praziquantel Tablets 600 mg [1]

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 600 mg praziquantel

3. LIST OF EXCIPIENTS

See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated Tablet
100 tablets
500 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}

[1] 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 below 30°C in a dry place. Protect from light.

For 100 count bottle pack: Should be used within 28 days after opening
For 500 count bottle pack: Should be used within 85 days, once opened

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

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church road
Andheri (East)
Mumbai – 400 059
India

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

NT004

13. MANUFACTURER'S BATCH NUMBER

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

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

Carton label/ Blisters (Alu-PVC/PVdC)

1. NAME OF THE MEDICINAL PRODUCT

Praziquantel Tablets 600 mg[2]

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 600 mg praziquantel

3. LIST OF EXCIPIENTS

See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated Tablet

9x10 tablets
10x10 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}

[2] 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 below 30°C in a dry place. Protect from light. Keep blisters in the provided outer carton to 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

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church road
Andheri (East)
Mumbai – 400 059
India

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

NT004

13. MANUFACTURER'S BATCH NUMBER

<Batch><Lot><BN> {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

Praziquantel Tablets 600 mg[3]

2. NAME OF THE SUPPLIER

Macleods Pharmaceuticals Limited

3. EXPIRY DATE

EXP {DD/MM/YYYY}

4. BATCH NUMBER

<Batch> {number}

[3] 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.