LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX 8 x 4g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ORNICURE 150 mg/g, powder for use in drinking water (all CMS except FR) ORNICURE, powder for use in drinking water (FR) Doxycycline hyclate

2. STATEMENT OF ACTIVE SUBSTANCES

150.0 mg doxycycline hyclate (equivalent to 130.0 mg of doxycycline) per 1 g powder.

3. PHARMACEUTICAL FORM

Powder for use in drinking water

4. PACKAGE SIZE

 $8 \times 4 g$

5. TARGET SPECIES

Pigeons (racing pigeons) and ornamental birds, particularly Psittaciformes (e.g. African grey parrots, Goffin's cockatoos, cockatiels)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In drinking water use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not authorised for use in birds intended for human consumption. Not for use in birds producing or intended to produce eggs for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP MM/YYYY

Once opened, use immediately. Do not store.

Once diluted or reconstituted according to directions, use within 24 hours.

11. SPECIAL STORAGE CONDITIONS

Following reconstitution, the medicated solutions should be protected from direct sunlight.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Label on jar (jar contains a 200 g bag)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ORNICURE 150 mg/g, powder for use in drinking water (all CMS except FR) ORNICURE, powder for use in drinking water (FR) Doxycycline hyclate

2. STATEMENT OF ACTIVE SUBSTANCES

150.0 mg doxycycline hyclate (equivalent to 130.0 mg of doxycycline) per 1 g powder.

3. PHARMACEUTICAL FORM

Powder for use in drinking water.

4. PACKAGE SIZE

200 g

5. TARGET SPECIES

Pigeons (racing pigeons) and ornamental birds, particularly Psittaciformes (e.g. African grey parrots, Goffin's cockatoos, cockatiels)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In drinking water use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not authorised for use in birds intended for human consumption. Not for use in birds producing or intended to produce eggs for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP MM/YYYY

Once opened, use by...

Once diluted or reconstituted according to directions, use within 24 hours.

11. SPECIAL STORAGE CONDITIONS

Tightly reclose the bag after opening in order to protect from light. Following reconstitution, the medicated solutions should be protected from direct sunlight.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

4 g Paper-PE-Alu-PE Sachet (packed per 8)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ORNICURE 150 mg/g, powder for use in drinking water for racing pigeons and ornamental birds (all CMS except FR)

ORNICURE, powder for use in drinking water for racing pigeons and ornamental birds (FR) Doxycycline hyclate

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

150 mg doxycycline hyclate (equivalent to 130 mg of doxycycline) per 1 g powder.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4 g

4. ROUTE(S) OF ADMINISTRATION

In drinking water use.

5. WITHDRAWAL PERIOD

Not authorised for use in birds intended for human consumption. Not authorised for use in birds producing or intended to produce eggs for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP MM/YYYY

Once opened, use immediately. Do not store.

Once diluted or reconstituted according to directions, use within 24 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

200 g Paper-PE-Alu-PE Bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ORNICURE 150 mg/g, powder for use in drinking water for racing pigeons and ornamental birds (all CMS except FR)

ORNICURE, powder for use in drinking water for racing pigeons and ornamental birds (FR) Doxycycline hyclate

2. STATEMENT OF ACTIVE SUBSTANCES

150.0 mg doxycycline hyclate (equivalent to 130.0 mg of doxycycline) per 1 g powder.

3. PHARMACEUTICAL FORM

Powder for use in drinking water

4. PACKAGE SIZE

200 g

5. TARGET SPECIES

Pigeons (racing pigeons) and ornamental birds, particularly Psittaciformes (e.g. African grey parrots, Goffin's cockatoos, cockatiels)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In drinking water use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not authorised for use in birds intended for human consumption. Not authorised for use in birds producing or intended to produce eggs for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP MM/YYYY

Once opened, use by...

Once diluted or reconstituted according to directions, use within 24 hours.

11. SPECIAL STORAGE CONDITIONS

Tightly reclose the bag after opening in order to protect from light.

Following reconstitution, the medicated solutions should be protected from direct sunlight.

- 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY
- 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

- 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"
- 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

17. MANUFACTURER'S BATCH NUMBER

Lot {number}