

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colixyme 22.5 MIU/g powder for use in drinking water

Colistin sulfate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Colistin (as sulfate) 22.5 MIU

3. PHARMACEUTICAL FORM

Powder for use in drinking water

4. PACKAGE SIZE

20 sachets of 615 MIU containing 27.3 g of product

20 sachets of 1020MIU containing 45.28 g of product. "

5. TARGET SPECIES Chicken, turkeys, cattle (calves) and pigs.

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

In drinking water use

Read the package leaflet before use

8. WITHDRAWAL PERIOD

Calves and pigs

Meat and offal: 1 day

Chickens and turkeys

Meat and offal: 1 day

Eggs: zero days

9. SPECIAL WARNINGS, IF NECESSARY

10. EXPIRY DATE

EXP{month/year}:

Once opened use immediately

Once diluted use within 24 hours

11. SPECIAL STORAGE CONDITIONS

Keep out of the sight and reach of children.

Keep the container tightly closed in order to protect from light,.

Do not use this veterinary medicinal product after the expiry date which is stated on the sachets.

Shelf-life after first opening the container: use immediately.

Shelf-life after dilution or reconstitution according to directions: 24 hours

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

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

For animal treatment only - to be supplied only by veterinary prescription.

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Andersen S.L. Avda. de la Llana, 123 08191 Rubí (SPAIN)

16. MARKETING AUTHORISATION NUMBER

17. MANUFACTURER’S BATCH NUMBER

Batch number:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colixyme 22.5 MIU/g powder for use in drinking water

Colistin sulfate

2. QUANTITY OF THE ACTIVE SUBSTANCE

Colistin (as sulfate) 22.5 MIU

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

615 MIU containing 27.3 g of product.

1020 MIU containing 45.28 g of product.

4. ROUTE OF ADMINISTRATION

In drinking water use

5. WITHDRAWAL PERIOD

“Calves and pigs

Meat and offal: 1 day

Chickens and turkeys

Meat and offal: 1 day

Eggs: zero days

6. BATCH NUMBER

Batch number:

7. EXPIRY DATE

EXP {month/year}:

Once opened use immediately

Once diluted use within 24 hours

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only