

1.3.1	Colistin sulphate	SI, CZ, RO, LV, PL, LT
SPC, Labeling and Package Leaflet	powder for oral solution 50 mg_g	

PARTICULARS TO APPEAR ON THE PACKAGE

Sachets, plastic container with plastic closure.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Giraxa 50 mg/g powder for oral solution for calves, piglets and chickens

Colistin sulphate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each gram of powder contains:

Active substance:

Colistin (as sulphate)* 50 mg (equivalent to 1 200 000 IU)

**50 mg of colistin sulphate is equivalent to 40 mg of colistin base*

3. PHARMACEUTICAL FORM

Powder for oral solution

4. PACKAGE SIZE

100 g

1000 g

5. TARGET SPECIES

Cattle (calves), pigs (piglets), chickens

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Giraxa powder is administered orally in drinking water.

8. WITHDRAWAL PERIOD

Calves, piglets, chickens: meat and offal: 1 day

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Not permitted for use in laying birds producing eggs for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

Shelf-life after first opening the immediate packaging: 4 months

Shelf-life after dilution or reconstitution according to directions: 18 hours

Information about the series and date of expiration are shown on the sealed edge of the bag.

11. SPECIAL STORAGE CONDITIONS

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

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, 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

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Batch: {number}

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