

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dehinexxa 30 mg/7.5 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette (0.35 ml) contains 30 mg of praziquantel and 7.5 mg of emodepside.

3. PACKAGE SIZE

1 x 0.35 ml
2 x 0.35 ml
3 x 0.35 ml
6 x 0.35 ml
40 x 0.35 ml

4. TARGET SPECIES

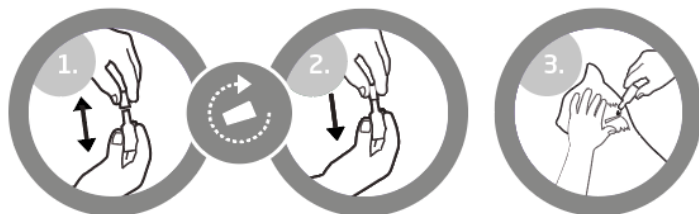
SMALL CATS
≥ 0.5 – 2.5 kg



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on use.



7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from light and moisture.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:
KRKA, d.d., Novo mesto

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{BAG}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dehinexxa



≥ 0.5 – 2.5 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

praziquantel/emodepside
30 mg/7.5 mg

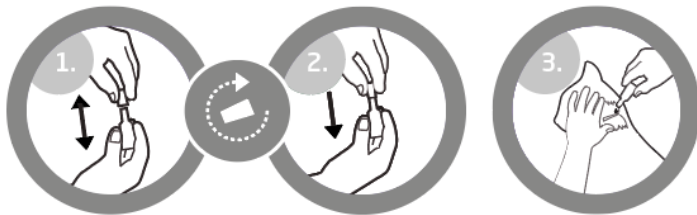
3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

KRKA



MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
{PIPETTE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dehinexxa



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

≥ 0.5 – 2.5 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}