

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Sachet of 1000 g - 500 g - 250 g – 25 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parofo 70 mg/g powder for use in drinking water, milk or milk replacer for pre-ruminant cattle and pigs.
Paromomycin (as sulfate).

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per gram:

Paromomycin sulfate	100 mg, equivalent to paromomycin base 70 mg or 70.000 IU of paromomycin activity
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3. PHARMACEUTICAL FORM

Powder for use in drinking water, milk or milk replacer.

4. PACKAGE SIZE

1000 g
500 g
250 g
25 g

5. TARGET SPECIES

Pre-ruminant cattle, pig.

6. INDICATION(S)

Treatment of gastro-intestinal infections caused by *Escherichia coli* susceptible to paromomycin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Pre-ruminant cattle
Meat and offal: 20 days
Pig
Meat and offal: 3 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP

Shelf life after first opening: 6 months. Once opened use by....
Medicated drinking water should be refreshed or replaced every 24 hours

11. SPECIAL STORAGE CONDITIONS

Product as packed for sales: do not store above 30°C.
After first opening: do not store above 25°C. Keep the sachet tightly closed
After reconstitution: do not store above 25°C.

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

Disposal: read the 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”
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Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

16. MARKETING AUTHORISATION NUMBER(S)
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17. MANUFACTURER’S BATCH NUMBER
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Lot: