ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parofor 175 mg/ml solution for injection for pigs.
Paromomycin sulfate

2. STATEMENT OF ACTIVE SUBSTANCES

Per ml:
Paromomycin sulfate 250 mg equivalent to paromomycin base 175 mg or 175.000 IU of paromomycin activity

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pigs (piglets).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 20 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Shelf life after first opening of the package: 28 days. Once opened use by….

11. SPECIAL STORAGE CONDITIONS

Product as packed for sale: Store the vials in the outer carton in order to protect from light.
After first opening: 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"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Huvepharma N.V.
Uitbreidingstraat 80
2600 Antwerpen
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 30282/4039

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Parofor 175 mg/ml solution for injection for pigs.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Huvepharma N.V.
Uitbreidingstraat 80
2600 Antwerpen
Belgium

Manufacturer responsible for batch release:

Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parofor 175 mg/ml solution for injection for pigs.
Paromomycin sulfate.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Per 1 ml:
Active substance:

Paromomycin sulfate	250 mg equivalent to paromomycin base 175 mg or 175.000 IU of paromomycin activity

Excipients:

Chlorocresol	1.0 mg
Sodium metabisulfite (E223)	3.0 mg

A clear yellow to amber solution.

4. INDICATION(S)

Paromomycin is indicated for the treatment of bacterial infections caused by pathogens which are susceptible to paromomycin, provided effective concentrations are achieved at the site of infection.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to paromomycin, other aminoglycosides or any of the excipients.
Do not use in cases with impaired function of the kidneys or liver.

6. ADVERSE REACTIONS

In rare occasions soft faeces has been observed.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

Aminoglycoside antibiotics such as paromomycin can cause oto- and nephrotoxicity.

7. TARGET SPECIES

Pigs (piglets).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For intramuscular use.
One injection per day for 3 to 5 days.

	Paromomycin sulfate/kg	*mL Parofor /weight*
Pigs Less than 50 kg	20 mg/kg (equivalent to 14000 IU)	0.4 mL/5 kg

Do not administer more than 3.8 ml per injection site.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage and to prevent under-dosing, body weight must be determined as accurately as possible. Repeated injections should be done in distinct injection sites.
The closures should not be broached more than 30 times. In order to prevent excessive broaching of the stopper, a suitable multiple dosing device should be used.

10. WITHDRAWAL PERIODS

Meat and offal: 20 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Product as packed for sale: Store the vials in the outer carton in order to protect from light.
After first opening: do not store above 25°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after “EXP”. The expiry date refers to the last day of that month.

Shelf life after first opening of the package: 28 days.

12. SPECIAL WARNING(S)

Special precautions for use in animals

In the event of a suspected *Pseudomonas aeruginosa* infection, the susceptibility of this bacterial target pathogen must be determined before starting treatment.
The use of the product should be combined with good management practices e.g. good hygiene, proper ventilation, no overstocking.
Since the product is potentially ototoxic and nephrotoxic, it is recommended to assess kidney function. Due to this risk of oto- and nephrotoxicity, the use of the product in neonates should be based on benefit-risk assessment by the responsible veterinarian.
Given the narrow margin of safety of aminoglycosides, the dosage should be reduced for overweight or dehydrated animals or animals suffering from renal insufficiency.

Prolonged or repeated use of the product should be avoided by improving management practices and through cleansing and disinfection.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. Official, national and regional antimicrobial policies should be taken into account when the product is used.
Aminoglycosides are considered as critical in human medicine. Consequently, they should not be used as a first intention treatment in veterinary medicine.

Use of the product deviating from the given instructions may increase the prevalence of bacteria resistant to paromomycin and may decrease the effectiveness of treatment with aminoglycosides due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This product contains paromomycin, chlorocresol and sodium metabisulphite which can cause allergic reactions in some people. People with known hypersensitivity (allergy) to aminoglycosides, chlorocresol and/or sulphites should avoid contact with the product.
This product may cause skin and eye irritation and therefore contact with skin and eyes should be avoided. If the product has come into contact with skin or eyes, rinse immediately with plenty of water. Seek medical attention if irritation persists.
In case of accidental injection, seek medical attention immediately.
Do not eat, drink or smoke while handling this product and wash hands after use.

Pregnancy

Laboratory studies in rat and rabbit have not produced any evidence of teratogenic, foetoxic, maternotoxic effects. The safety of the product during pregnancy and

lactation has not been established in target species. Therefore, the use of the veterinary medicinal product should be based on a risk/benefit assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

Do not use concurrently with diuretics and potentially oto- or nephrotoxic substances. General anaesthetics and muscle relaxants increase the neuromuscular blocking effect of aminoglycosides, which can lead to acute paralysis and apnoea.

Overdose

None known.

Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Environmental properties

The active ingredient paromomycin sulfate is very persistent in the environment.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack size: bottle of 100 ml.

Approved: 18 October 2018