ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with 1 glass or PET bottle of 100 ml
Box with 1 glass or PET bottle of 250 ml
Box with 10 PET bottles of 100 ml
Box with 30 PET bottles of 100 ml
Box with 6 PET bottles of 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMOPEN 300 mg/ml suspension for injection for cattle, pigs and horses
Benzylpenicillin (procaine) monohydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance: Benzylpenicillin (procaine) monohydrate 300 mg (corresponding to 170 mg benzylpenicillin).

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml
250 ml
10x100 ml
30x100 ml
6x250 ml

5. TARGET SPECIES

Cattle, pigs and horses.

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods
Meat and offal: Cattle 6 days.
Pigs 4 days.
Horses 6 months.

Milk: Cattle 4 days (96 hours).
Not authorised for use in horses producing milk for human consumption.

9. SPECIAL WARNINGS, IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user warnings.

10. EXPIRY DATE

EXP {month /year}

Shelf-life after first opening the container: 28 days.
Once opened, use by _____

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C - 8°C).
Do not freeze.
Keep the bottle in the outer carton in order to protect from light.

12. SPECIFIC 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

FATRO S.p.A
Via Emilia, 285
Ozzano Emilia - Bologna
Italy

16. MARKETING AUTHORISATION NUMBERS

Vm 11557/4005

17. MANUFACTURER'S BATCH NUMBER

LOT. {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
100 ml label
250 ml label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMOPEN 300 mg/ml suspension for injection for cattle, pigs and horses
Benzylpenicillin (procaine) monohydrate

2. STATEMENT OF THE ACTIVE SUBSTANCES

Each ml contains:
Active substance: Benzylpenicillin (procaine) monoihydrate 300 mg (corresponding to 170 mg benzylpenicillin).

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs and horses.

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods
Meat and offal: Cattle 6 days.
Pigs 4 days.
Horses 6 months.

Milk: Cattle 4 days (96 hours)
Not authorised for use in horses producing milk 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 container: 28 days.
Once opened, use by _____.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C - 8°C).
Do not freeze.
Keep the bottle in the outer carton in order to protect from light.

12. SPECIFIC 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

FATRO S.p.A
Via Emilia, 285
Ozzano Emilia - Bologna
Italy

16. MARKETING AUTHORISATION NUMBERS

Vm 11557/4005

17. MANUFACTURER'S BATCH NUMBER

LOT. {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

PRIMOPEN
300 mg/ml suspension for injection for cattle, pigs and horses

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

Marketing authorisation holder and manufacturer responsible for batch release:
FATRO S.p.A
Via Emilia, 285
Ozzano Emilia - Bologna
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMOPEN 300 mg/ml suspension for injection for cattle, pigs and horses
Benzylpenicillin (procaine) monohydrate

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substance:	
Benzylpenicillin (procaine) monohydrate (corresponding to 170 mg benzylpenicillin)	300 mg
Excipients:	
Sodium formaldehyde sulfoxylate	2.50 mg
Sodium methyl parahydroxybenzoate (E219)	1.15 mg
Disodium edetate	0.55 mg

White to almost white, homogeneous suspension.

4. INDICATIONS

For the treatment of infections caused by penicillin-sensitive bacteria.

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substance, to cephalosporins, procaine or to any of the excipients.
Do not use in rabbits, guinea pigs, hamsters or gerbils.
Do not use intravenously.

6. ADVERSE REACTIONS

Allergies to penicillin have been observed but these are very rare.
Potentially fatal reactions associated with the administration of procaine penicillin in horses have been observed in very rare cases. Less serious symptoms of procaine toxicity include locomotor and behavioural changes.
In pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

In sucking and fattening pigs, administration of products containing procaine penicillin may cause transient pyrexia, vomiting shivering, listlessness and incoordination.

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle, pigs and horses.

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

For intramuscular use.
Administer by deep intramuscular injection once daily for up to 5 days.
The recommended daily dose is 12 mg of benzylpenicillin procaine/kg body weight equivalent to 1 ml/25 kg body weight/day.
The maximum volume to be administered per injection site is 15.5 ml in cattle and 3.2 ml in pigs.
To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

Shake well before use.
The bottle may be broached up to 20 times.

9. ADVICE ON CORRECT ADMINISTRATION

Clean the area of the injection site and swab with spirit.
Do not use the same injection site more than once during a course of treatment.

10. WITHDRAWAL PERIOD(S)

Meat and offal: Cattle 6 days.
Pigs 4 days.
Horses 6 months.

Milk: Cattle 4 days (96 hours).
Not authorised for use in horses producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2°C - 8°C).
Do not freeze.

Keep the bottle in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNINGS

Special warnings for each target species
The product will not be effective against beta lactamase producing organisms.

Special precautions for use in animals
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.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to benzylpenicillin and may decrease the effectiveness of treatment with other penicillins and cephalosporins due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins and cephalosporins may cause hypersensivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances are occasionally serious.
Do not handle this product if you know that you are sensitised or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure, taking all recommended precautions.
If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes, or difficulty breathing are more serious symptoms and require urgent medical attention.
In case of accidental contact with eyes, rinse immediately with copious amounts of water.
Accidental spillage on the skin should be washed immediately with soap and water.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation
Laboratory studies in animals have not provided evidence of teratogenic, fetotoxic or maternal toxic effects.
The safety of this product has not been established during pregnancy and lactation.
Use only in accordance with the benefit / risk assessment of the responsible veterinarian during pregnancy and lactation.
See also section “Adverse reactions”.

Interaction with other medicinal products and other forms of interaction

Benzylpenicillin is bactericidal. Avoid concurrent use of bactericidal and bacteriostatic antibiotics.
There is cross-resistance between penicillins and other beta-lactam antibiotics.

Overdose (symptoms, emergency procedures, antidotes)
Penicillin is a compound with a very high therapeutic index. However, overdosing in young animals and horses should be avoided in order to prevent procaine poisoning.

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

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 product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack-sizes:
1 x 100 ml glass or PET bottle
1 x 250 ml glass or PET bottle
10 x 100 ml PET bottles
30 x 100 ml PET bottles
6 x 250 ml PET bottles

Not all pack sizes may be marketed.

Veterinary use. To be supplied only on veterinary prescription.

Approved 16 September 2020