∑[Version 9,03/2022]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Valeramol 200 mg/g oral powder for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains

Active substance:
Paracetamol 200 mg

Excipient:

Qualitative composition of excipients and other constituents
Glucose monohydrate

White or almost white, crystalline powder

3. CLINICAL INFORMATION

3.1 Target species

Pigs

3.2 Indications for use for each target species

Symptomatic treatment of fever in the context of respiratory diseases in combination with an appropriate anti-infective therapy, if necessary.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animal with severe hepatic impairment.
Do not use in animal with severe renal impairment. See also section 3.8.
Do not use in animal suffering from dehydration or hypovolemia.

3.4 Special warnings

Animals with reduced water intake and/or disturbed general condition must be treated parenterally.
A decrease of hyperthermia is expected 12-24 hours after onset of treatment depending on the consumption of medicated water/feed.
In case of combined viral and bacterial aetiology of the disease, an appropriate anti-infective therapy should be given concomitantly.
An administration to piglets before weaning is not appropriate due to inconsistent feed and water intake. For those piglets, parenteral treatment is recommended.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of gloves, a mask and goggles to protect the face and eyes should be worn when handling the veterinary medicinal product.

In case of accidental self-exposure or spillage onto skin or in the eyes, flush immediately with a large amount of water. If symptoms persist seek medical advice immediately and show the package leaflet or the label to the physician.

To rule out any risk of ingestion it is recommended not to eat, or drink while using the product and to wash the hands after use.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to paracetamol should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Loose stool*

*Transient loose stool (at therapeutic doses and persisting up to 8 days after the discontinuation of treatment). It does not have any effect on general condition of animals, and resolves without any specific treatment.)

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laboratory studies in mice and rats have not produced any evidence of teratogenic or foetotoxic effects. No adverse effects were observed after administration to pregnant or lactating sows of doses up to three times the recommended dose.

Can be used during pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration of nephrotoxic drugs should be avoided.

3.9 Administration routes and dosage

In drinking water use. In-feed use.

The daily dose is 30 mg of paracetamol per kg body weight, as long as the pigs are suffering from pyrexia for a maximum duration treatment of 5 days.

30 mg paracetamol per kg body weight daily corresponds to 1.5 g of the veterinary medicinal product per 10 kg body weight daily.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated weighing equipment for the administration of the calculated amount of the product is recommended.

In drinking water use:

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{150 mg of the product / kg body weight per day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water intake (L/animal)}} = \text{mg of the product per litre of drinking water}$$

The intake of medicated water depends on the clinical condition of the animals. In order to obtain a correct dosage, the concentration of paracetamol may need to be adjusted accordingly.

Recommendation for dissolution:

The maximum solubility of the product in (soft/hard) water at 5ºC to 25ºC is 42 g /L.

Prepare the solution with fresh tap water immediately before use. Prepare a pre-solution with the required amount of product using a sufficient quantity of water in order to not exceed the maximum solubility. Stir for five minutes to ensure complete dissolution. Then adjust the remaining quantity of water to achieve the concentration required. Stir again to ensure a homogeneous solution.

For stock solutions and when using a proportioner, take care not to exceed the maximum solubility which can be achieved under the given conditions. Adjust flow rate setting of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.
Water uptake should be monitored at frequent intervals during medication. The medicated drinking water should be the sole source of drinking water for the treatment duration. Any medicated drinking water which is not consumed within 24 hours should be discarded.

After the end of the medication period, the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

In liquid feed use:

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{150 mg of the product / kg body weight per day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily feed intake (kg/animal)}} = \text{mg of the product per kg of feed}$$

In case that the daily feed ration is supplied in two meals, half of the daily dose should be mixed into each meal accordingly.

Recommendation for preparation:

Prepare a pre-solution with the required amount of product. Take sufficient quantity of water in order to not exceed a maximum concentration of 42 g product per litre water in that pre-solution. The pre-solution must then be mixed into the liquid feed. The liquid feed should be continuously stirred during the preparation and the distribution to the animals. Preparation of medicated liquid feed should provide an amount to be consumed within the next 24 hours. Any unused medicated liquid feed should be discarded after 24 hours.

In dry feed use:

The product is only intended for the treatment of individual pigs on farms where a small number of pigs are to receive treatment. If clinical signs of fever and respiratory diseases are observed in a larger group, the animals should be treated via drinking water or with medicated feed.
The daily dose should be administered in two meals. Per meal, half of the daily dose should be mixed into approximately 200–500 g of feed followed by thoroughly mixing this pre-mixture into the remainder of the meal. The feed containing the oral powder should be provided as the sole ration for the treatment period. It must be prepared just before administration to the animals. Pigs to be treated should be separated and treated individually. The dry feed containing the product which is not consumed must be disposed of with other waste feed and not given to other animals.

The pig to be treated should be weighed and the amount of feed that the pig is likely to consume should be estimated, based on a daily feed intake equivalent to 5% of body weight. Consideration must be given to pigs whose daily feed intake is reduced or restricted. The correct quantity of the product should be added to the estimated quantity of feed for each pig, in a bucket or similar receptacle, and thoroughly mixed. To ensure a better homogeneity, the veterinary medicinal product should only be mixed with a dry non-pelleted feed.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

After administration of 5 times the recommended dose of paracetamol, loose stool with solid particles may occasionally occur. It does not have any effect on general body condition of animals.
Acetylcysteine can be used in case of accidental overdose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: Zero days for in drinking water use
Meat and offal: 1 day for in dry feed and liquid feed use

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QN02BE01

4.2 Pharmacodynamics

Paracetamol or acetaminophen or N-acetyl-para-aminophenol is a paraminophenol derivative with analgesic and antipyretic properties. Its antipyretic effect may be explained by its ability to inhibit brain cyclo-oxygenases. Paracetamol is only a weak inhibitor of COX-1 synthesis and, thus, no gastro-intestinal side effects and has no effect on platelet-aggregation.

4.3 Pharmacokinetics

Absorption:
In drinking water use:
Paracetamol is rapidly and almost completely absorbed after oral administration (bioavailability of about 90% after administration in the drinking water). Peak concentrations are reached in a little less than 2 hours after ingestion.

In-feed use:
After a single oral administration of the product in feed, at 15 mg/kg, the bioavailability is 76 %, the peak of paracetamol concentration (C_{max}), 3.6 µg/ml, is reached 2.4 hours after the administration.

Metabolism:
Paracetamol is mainly metabolised in the liver. The two major metabolic pathways are conjugation to glucuronate and conjugation to sulphate. The latter route is rapidly saturable at dosages higher than therapeutic doses. A minor pathway, catalysed by cytochrome P450, leads to the formation of the intermediary reagent, N-acetylbenzoquinoneimine which, under normal conditions of use, is rapidly detoxified by reduced glutathione and removed in urine after conjugation with cystein and mercapturic acid. On the contrary, after massive intoxication, the quantity of this toxic metabolite is increased.

Elimination:
Paracetamol is mainly eliminated in the urine. In the pig, 63 – 70 % of the ingested dose is eliminated by the kidneys in 24 hours mainly conjugated to glucuronate and sulphate.
Less than 5% is eliminated in unchanged form. The elimination half-life is approximately 4 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months
Shelf life after first opening the immediate packaging: 3 months
Shelf life after dissolution in the drinking water according to directions: 24 hours
Shelf life after incorporation into liquid feed: 24 hours
Shelf life after incorporation into dry feed: use immediately

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

LDPE/Alu/PET bag (1 kg or 6 kg)
HDPE bottle with neck for push on LDPE tear band lid (150 g) Cardboard box containing 10 x 150 g in a white HDPE bottle with neck for push on LDPE tear band lid

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned. Medicines should not be disposed of via wastewater.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Pharmanovo Veterinärarzneimittel GmbH

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (10 x 150 g)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Valeramol 200 mg/g oral powder

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:
Paracetamol 200 mg

3. PACKAGE SIZE

10 x 150 g

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use. In-feed use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: Zero days for in drinking water use
Meat and offal: 1 day for in dry feed and liquid feed use

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months
Once dissolved in drinking water use within 24 hours.
Once incorporated into liquid feed use within 24 hours.
Once incorporated into dry feed use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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

Pharmanovo Veterinärarzneimittel GmbH

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

150 g container
1 kg or 6 kg bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Valeramol 200 mg/g oral powder

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:
Paracetamol 200 mg

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

In drinking water use. In-feed use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: Zero days for in drinking water use
Meat and offal: 1 day for in dry feed and liquid feed use

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.
Once dissolved in drinking water use within 24 hours.
Once incorporated into liquid feed use within 24 hours.
Once incorporated into dry feed use immediately.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Pharmanovo Veterinärarzneimittel GmbH

9. BATCH NUMBER

Lot {number}

Additional Information, based on Article 13 Regulation (EU) 2019/6:

PACKAGE SIZE

150 g
1 kg
6 kg

5. INDICATIONS

THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

MARKETING AUTHORISATION NUMBERS

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

1 kg or 6 kg bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Valeramol 200 mg/g oral powder for pigs

2. COMPOSITION

Each g contains

Active substance:
Paracetamol 200 mg

Excipient:
Glucose monohydrate

White or almost white, crystalline powder

3. PACKAGE SIZE

1 kg
6 kg

4. TARGET SPECIES

Pigs

5. INDICATIONS FOR USE

Indications for use
Symptomatic treatment of fever in the context of respiratory diseases in combination with an appropriate anti-infective therapy, if necessary.

6. CONTRAINDICATIONS

Contraindications
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animal with severe hepatic impairment.
Do not use in animal with severe renal impairment. See also section “Interaction with other medicinal products and other forms of interaction”.
Do not use in animal suffering from dehydration or hypovolemia.

7. SPECIAL WARNINGS

Special warnings

Special warnings:
Animals with reduced water intake and/or disturbed general condition have to be treated parenterally.
A decrease of hyperthermia is expected 12-24 hours after onset of treatment depending on the consumption of medicated water/feed.
In case of combined viral and bacterial aetiology of the disease, an appropriate anti-infective therapy should be given concomitantly.
An administration to piglets before weaning is not appropriate due to inconsistent feed and water intake. For those piglets, parenteral treatment is recommended.

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of gloves, a mask and goggles to protect the face and eyes should be worn when handling the veterinary medicinal product.

In case of accidental self-exposure or spillage onto skin or in the eyes, flush immediately with a large amount of water. If symptoms persist seek medical advice immediately and show the package leaflet or the label to the physician.

To rule out any risk of ingestion it is recommended not to eat, or drink while using the product and to wash the hands after use.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to Paracetamol should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
Laboratory studies in mice and rats have not produced any evidence of teratogenic or foetotoxic effects. No adverse effects were observed after administration to pregnant or lactating sows of doses up to three times the recommended dose.

Can be used during pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction:
Concurrent administration of nephrotoxic drugs should be avoided.

Overdose:
After administration of 5 times the recommended dose of paracetamol, loose stool with solid particles may occasionally occur. It does not have any effect on general body condition of animals.
Acetylcysteine can be used in case of accidental overdose.

Special restrictions for use and special conditions for use:
Not applicable.

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

8. ADVERSE EVENTS

Adverse events

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Loose stool*

*Transient loose stool (at therapeutic doses and persisting up to 8 days after the discontinuation of treatment). It does not have any effect on general condition of animals, and resolves without any specific treatment.)

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder, the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In drinking water use. In-feed use.

The daily dose is 30 mg of paracetamol per kg body weight, as long as the pigs are suffering from pyrexia for a maximum duration treatment of 5 days.
30 mg paracetamol per kg body weight daily corresponds to 1.5 g of the veterinary medicinal product per 10 kg body weight daily.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated weighing equipment for the administration of the calculated amount of the product is recommended.

In drinking water use:
Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{150 mg of the product / kg body weight per day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water intake (L/animal)}} = \text{mg of the product per litre of drinking water}$$

The intake of medicated water depends on the clinical condition of the animals. In order to obtain a correct dosage, the concentration of paracetamol may need to be adjusted accordingly.

Recommendation for dissolution:

The maximum solubility of the product in (soft/hard) water at 5ºC to 25ºC is 42 g /L.

Prepare the solution with fresh tap water immediately before use. Prepare a pre-solution with the required amount of product using a sufficient quantity of water in order to not exceed the maximum solubility. Stir for five minutes to ensure complete dissolution. Then adjust the remaining quantity of water to achieve the concentration required. Stir again to ensure a homogeneous solution.

For stock solutions and when using a proportioner, take care not to exceed the maximum solubility which can be achieved under the given conditions. Adjust flow rate setting of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.
Water uptake should be monitored at frequent intervals during medication. The medicated drinking water should be the sole source of drinking water for the treatment duration. Any medicated drinking water which is not consumed within 24 hours should be discarded.

After the end of the medication period, the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

In liquid feed use:
Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{150 mg of the product / kg body weight per day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily feed intake (kg/animal)}} = \text{mg of the product per kg of feed}$$

In case that the daily feed ration is supplied in two meals, half of the daily dose should be mixed into each meal accordingly.

Recommendation for preparation:

Prepare a pre-solution with the required amount of product. Take sufficient quantity of water in order to not exceed a maximum concentration of 42 g product per litre water in that pre-solution. The pre-solution must then be mixed into the liquid feed. The liquid feed should be continuously stirred during the preparation and the distribution to the animals. Preparation of medicated liquid feed should provide an amount to be consumed within the next 24 hours. Any unused medicated liquid feed should be discarded after 24 hours.

In dry feed use:
The product is only intended for the treatment of individual pigs on farms where a small number of pigs are to receive treatment. If clinical signs of fever and respiratory diseases are observed in a larger group, the animals should be treated via drinking water or with medicated feed.
The daily dose should be administered in two meals. Per meal, half of the daily dose should be mixed into approximately 200–500 g of feed followed by thoroughly mixing this pre-mixture into the remainder of the meal. The feed containing the oral powder should be provided as the sole ration for the treatment period. It must be prepared just before administration to the animals. Pigs to be treated should be separated and treated individually. The dry feed containing the product which is not consumed must be disposed of with other waste feed and not given to other animals.

The pig to be treated should be weighed and the amount of feed that the pig is likely to consume should be estimated, based on a daily feed intake equivalent to 5% of body weight. Consideration must be given to pigs whose daily feed intake is reduced or restricted. The correct quantity of the product should be added to the estimated quantity of feed for each pig, in a bucket or similar receptacle, and thoroughly mixed. To ensure a better homogeneity, the veterinary medicinal product should only be mixed with a dry non-pelleted feed.

10. ADVICE ON CORRECT ADMINISTRATION

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: Zero days for in drinking water use
Meat and offal: 1 day for in dry feed and liquid feed use

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater. Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes
LDPE/Alu/PET bag (1 kg or 6 kg)
HDPE bottle with neck for push on LDPE tear band lid (150 g)
Cardboard box containing 10 x 150 g in a white HDPE bottle with neck for push on LDPE tear band lid

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Contact details

Marketing authorisation holder:
Pharmanovo Veterinärarzneimittel GmbH
Liebochstrasse 9
8143 Dobl
Austria

Manufacturer responsible for batch release:
AniMed Service AG
Liebochstrasse 9
8143 Dobl
Austria

Local representatives and contact details to report suspected adverse reactions:
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below:

To be completed during national phase.

Danmark
{Navn}
<{Adresse}
DK-0000 {by}>
Tlf: + {Telefonnummer}
<{E-mail}>

Lietuva
{pavadinimas}
<{adresas}
LT {pašto indeksas} {miestas}>
Tel: +370{telefono numeris}
<{E-mail}>

Deutschland
{Name}
<{Anschrift}
DE-00000 {Stadt}>
Tel: + {Telefonnummer}
<{E-mail}>

Eesti
(Nimi)
<(Aadress)
EE - (Postiindeks) (Linn)>
Tel: +(Telefoninumber)
<{E-mail}>

France
{Nom}
<{Adresse}
FR-00000 {Localité}>
Tél: + {Numéro de téléphone}
<{E-mail}>

Latvija
{Nosaukums}
<{Adrese}
{Pilsēta}, LV{Pasta indekss }>
Tel: + {Telefona numurs}
<{E-mail}>

Magyarország
{Név}
<{Cím}
HU-0000 {Város}>
Tel.: + {Telefonszám}
<{E-mail}>

Österreich
{Name}
<{Anschrift}
A-00000 {Stadt}>
Tel: + {Telefonnummer}
<{E-mail}>

Polska
{Nazwa/ Nazwisko:}
<{Adres:}
PL – 00 000{Miasto:}>
Tel.: + {Numer telefonu:}
<{E-mail}>

18. OTHER INFORMATION

Other information
To be completed during national phase.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the immediate packaging: 3 months
Shelf life after dissolution in the drinking water according to directions: 24 hours
Shelf life after incorporation into liquid feed: 24 hours
Shelf life after incorporation into dry feed: use immediately

21. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Valeramol 200 mg/g oral powder for pigs

2. Composition

Each g contains

Active substance:
Paracetamol 200 mg

Excipient:
Glucose monohydrate

White or almost white, crystalline powder

3. Target species

Pigs

4. Indications for use

Symptomatic treatment of fever in the context of respiratory diseases in combination with an appropriate anti-infective therapy, if necessary.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animal with severe hepatic impairment.
Do not use in animal with severe renal impairment. See also section “Interaction with other medicinal products and other forms of interaction”.
Do not use in animal suffering from dehydration or hypovolemia.

6. Special warnings

Special warnings:
Animals with reduced water intake and/or disturbed general condition must be treated parenterally.
A decrease of hyperthermia is expected 12-24 hours after onset of treatment depending on the consumption of medicated water/feed.
In case of combined viral and bacterial aetiology of the disease, an appropriate anti-infective therapy should be given concomitantly.
An administration to piglets before weaning is not appropriate due to inconsistent feed and water intake. For those piglets, parenteral treatment is recommended.

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of gloves, a mask and goggles to protect the face and eyes should be worn when handling the veterinary medicinal product.

In case of accidental self-exposure or spillage onto skin or in the eyes, flush immediately with a large amount of water.
If symptoms persist seek medical advice immediately and show the package leaflet or the label to the physician.

To rule out any risk of ingestion it is recommended not to eat, or drink while using the product and to wash the hands after use.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to Paracetamol should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
Laboratory studies in mice and rats have not produced any evidence of teratogenic or foetotoxic effects. No adverse effects were observed after administration to pregnant or lactating sows of doses up to three times the recommended dose.

Can be used during pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction:
Concurrent administration of nephrotoxic drugs should be avoided.

Overdose:
After administration of 5 times the recommended dose of paracetamol, loose stool with solid particles may occasionally occur. It does not have any effect on general body condition of animals.
Acetylcysteine can be used in case of accidental overdose.

Special restrictions for use and special conditions for use:
Not applicable.

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

7. Adverse events

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Loose stool*

*Transient loose stool (at therapeutic doses and persisting up to 8 days after the discontinuation of treatment). It does not have any effect on general condition of animals, and resolves without any specific treatment.)

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder, the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

8. Dosage for each species, routes and method of administration

In drinking water use. In-feed use.

The daily dose is 30 mg of paracetamol per kg body weight, as long as the pigs are suffering from pyrexia for a maximum duration treatment of 5 days.
30 mg paracetamol per kg body weight daily corresponds to 1.5 g of the veterinary medicinal product per 10 kg body weight daily.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated weighing equipment for the administration of the calculated amount of the product is recommended.

In drinking water use:
Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{150 mg of the product / kg body weight per day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water intake (L/animal)}} = \text{mg of the product per litre of drinking water}$$

The intake of medicated water depends on the clinical condition of the animals. In order to obtain a correct dosage, the concentration of paracetamol may need to be adjusted accordingly.

Recommendation for dissolution:

The maximum solubility of the product in (soft/hard) water at 5ºC to 25ºC is 42 g /L.

Prepare the solution with fresh tap water immediately before use. Prepare a pre-solution with the required amount of product using a sufficient quantity of water in order to not exceed the maximum solubility. Stir for five minutes to ensure complete dissolution. Then adjust the remaining quantity of water to achieve the concentration required. Stir again to ensure a homogeneous solution.

For stock solutions and when using a proportioner, take care not to exceed the maximum solubility which can be achieved under the given conditions. Adjust flow rate setting of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.
Water uptake should be monitored at frequent intervals during medication. The medicated drinking water should be the sole source of drinking water for the treatment duration. Any medicated drinking water which is not consumed within 24 hours should be discarded.

After the end of the medication period, the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

In liquid feed use:
Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{150 mg of the product / kg body weight per day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily feed intake}} = \text{mg of the product per kg of feed}$$

In case that the daily feed ration is supplied in two meals, half of the daily dose should be mixed into each meal accordingly.

Recommendation for preparation:

Prepare a pre-solution with the required amount of product. Take sufficient quantity of water in order to not exceed a maximum concentration of 42 g product per litre water in that pre-solution. The pre-solution must then be mixed into the liquid feed. The liquid feed should be continuously stirred during the preparation and the distribution to the animals. Preparation of medicated liquid feed should provide an amount to be consumed within the next 24 hours. Any unused medicated liquid feed should be discarded after 24 hours.

In dry feed use:
The product is only intended for the treatment of individual pigs on farms where a small number of pigs are to receive treatment. If clinical signs of fever and respiratory diseases are observed in a larger group, the animals should be treated via drinking water or with medicated feed.
The daily dose should be administered in two meals. Per meal, half of the daily dose should be mixed into approximately 200–500 g of feed followed by thoroughly mixing this pre-mixture into the remainder of the meal. The feed containing the oral powder should be provided as the sole ration for the treatment period. It must be prepared just before administration to the animals. Pigs to be treated should be separated and treated individually. The dry feed containing the product which is not consumed must be disposed of with other waste feed and not given to other animals.

The pig to be treated should be weighed and the amount of feed that the pig is likely to consume should be estimated, based on a daily feed intake equivalent to 5% of body weight. Consideration must be given to pigs whose daily feed intake is reduced or restricted. The correct quantity of the product should be added to the estimated quantity of feed for each pig, in a bucket or similar receptacle, and thoroughly mixed. To ensure a better homogeneity, the veterinary medicinal product should only be mixed with a dry non-pelleted feed.

9. Advice on correct administration

10. Withdrawal periods

Meat and offal: Zero days for in drinking water use
Meat and offal: 1 day for in dry feed and liquid feed use

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 months
Shelf life after dissolution in the drinking water according to directions: 24 hours
Shelf life after incorporation into liquid feed: 24 hours
Shelf life after incorporation into dry feed: use immediately

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

LDPE/Alu/PET bag (1 kg or 6 kg)
HDPE bottle with neck for push on LDPE tear band lid (150 g)
Cardboard box containing 10 x 150 g in a white HDPE bottle with neck for push on LDPE tear band lid

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:
Pharmanovo Veterinärarzneimittel GmbH
Liebochstrasse 9
8143 Dobl
Austria

Manufacturer responsible for batch release:
AniMed Service AG
Liebochstrasse 9
8143 Dobl
Austria

Local representatives and contact details to report suspected adverse reactions:
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below:

To be completed during national phase.

Danmark
{Navn}
<{Adresse}
DK-0000 {by}>
Tlf: + {Telefonnummer}
<{E-mail}>

Deutschland
{Name}
<{Anschrift}
DE-00000 {Stadt}>
Tel: + {Telefonnummer}
<{E-mail}>

Eesti
(Nimi)
<(Aadress)
EE - (Postiindeks) (Linn)>
Tel: +(Telefoninumber)
<{E-mail}>

France
{Nom}
<{Adresse}
FR-00000 {Localité}>
Tél: + {Numéro de téléphone}
<{E-mail}>

Latvija
{Nosaukums}
<{Adrese}
{Pilsēta}, LV{Pasta indekss }>
Tel: + {Telefona numurs}
<{E-mail}>

Lietuva
{pavadinimas}
<{adresas}
LT {pašto indeksas} {miestas}>
Tel: +370{telefono numeris}
<{E-mail}>

Magyarország
{Név}
<{Cím}
HU-0000 {Város}>
Tel.: + {Telefonszám}
<{E-mail}>

Österreich
{Name}
<{Anschrift}
A-00000 {Stadt}>
Tel: + {Telefonnummer}
<{E-mail}>

Polska
{Nazwa/ Nazwisko:}
<{Adres:}
PL – 00 000{Miasto:}>
Tel.: + {Numer telefonu:}
<{E-mail}>

17. Other information

To be completed during national phase.