LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Sachet of 100 g, 300 g, 400 g and 1 kg.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rhemox 500 mg/g powder for use in drinking water for pigs, chicken broilers, duck broilers and turkeys for meat production [AT, BE, BG, CY, CZ, DE, EL, ES, HU, IE, IT, NL, PT, RO, SI, SK, UK]
Rhemox 500 mg/g powder for use in drinking water for pigs, chickens, ducks and turkeys [PL]
Rhemox 435.6 mg/g powder for use in drinking water for pigs, chicken broilers, duck broilers and turkeys for meat production [FR]
Rhemox vet [DK, SE]
Rhemox vet 500 mg/g powder for use in drinking water [FI]
Amoxicillin trihydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Amoxicillin trihydrate (Equivalent to 435.6 mg Amoxicillin)	500 mg

"Only for France:"

Amoxicillin (as trihydrate) (Equivalent to 500 mg of Amoxicillin trihydrate)	435.6 mg

3. PHARMACEUTICAL FORM

Powder for use in drinking water.

4. PACKAGE SIZE

100 g
300 g
400 g
1 kg

5. TARGET SPECIES

Pigs
Chicken (broiler), duck (duck broiler) and turkey (turkey for meat production)

6. INDICATION(S)

Pigs: Treatment of infections caused by strains of *Streptococcus suis* susceptible to amoxicillin.

Chicken broilers, duck broilers and turkeys for meat production: Treatment of pasteurellosis and colibacillosis caused by strains of *Pasteurella spp*. and *Escherichia coli* sensitive to amoxicillin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For administration in drinking water.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: Pigs: 6 days
Chickens: 1 day.
Turkeys: 5 days
Ducks: 9 days.
Not authorised for use in birds producing eggs for human consumption and within 4 weeks before onset of the laying period.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Shelf-life after first opening the container: For immediate use.
Shelf life after reconstitution in water according to directions: 24 hours.
Once broached, for immediate use

11. SPECIAL STORAGE CONDITIONS

Store below 25 ºC.
Protect from light.
Store in a dry place.

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

Disposal: read 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.
Administration by a veterinary surgeon, or under their direct responsibility.

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

Industrial Veterinaria, S.A.
Esmeralda, 19
E-08950 Esplugues de Llobregat (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 36547/4005

17. MANUFACTURER'S BATCH NUMBER

Batch

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Rhemox 500 mg/g powder for use in drinking water for pigs, chicken broilers, duck broilers and turkeys for meat production [AT, BE, BG, CY, CZ, DE, EL, ES, HU, IE, IT, NL, PT, RO, SI, SK, UK]
Rhemox 500 mg/g powder for use in drinking water for pigs, chickens, ducks and turkeys [PL]
Rhemox 435.6 mg/g powder for use in drinking water for pigs, chicken broilers, duck broilers and turkeys for meat production [FR]
Rhemox vet [DK, SE]
Rhemox vet 500 mg/g powder for use in drinking water [FI]
Amoxicillin trihydrate

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

Marketing authorisation holder:
Industrial Veterinaria S.A.
Esmeralda, 19
E-08950 Esplugues de Llobregat (Barcelona)
Spain

Manufacturer responsible for batch release:
aniMedica Herstellungs GmbH
Pappelstr. 7 72160 Horb a. N
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rhemox 500 mg/g powder for use in drinking water for pigs, chicken broilers, duck broilers and turkeys for meat production [AT, BE, BG, CY, CZ, DE, EL, ES, HU, IE, IT, NL, PT, RO, SI, SK, UK]

Rhemox 500 mg/g powder for use in drinking water for pigs, chickens, ducks and turkeys [PL]

Rhemox 435.6 mg/g powder for use in drinking water for pigs, chicken broilers, duck broilers and turkeys for meat production [FR]

Rhemox vet [DK, SE]

Rhemox vet 500 mg/g powder for use in drinking water [FI]

Amoxicillin trihydrate

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

Each gram contains:

Active substance:
Amoxicillin trihydrate 500 mg
(Equivalent to 435.6 mg Amoxicillin)

"Only for France:"
Amoxicillin (as trihydrate) 435.6 mg
(Equivalent to 500 mg of Amoxicillin trihydrate)

Excipient:
Citric acid

Fine and homogeneous white or slightly creamy powder.

4. INDICATION(S)

Pigs: Treatment of infections caused by strains of *Streptococcus suis* susceptible to amoxicillin.
Chicken broilers, duck broilers and turkeys for meat production: Treatment of pasteurellosis and colibacillosis caused by strains of *Pasteurella spp*. and *Escherichia coli* sensitive to amoxicillin.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to penicillins, to other beta-lactams or to the excipient.
Do not use orally in rabbits, guinea pigs, hamsters or other small herbivores, given that amoxicillin, as for all aminopenicillins, has deleterious effects on caecal bacteria.
Do not use in horse given that amoxicillin, as all aminopenicillins, has an important effect on caecal bacteria.
Do not use orally in animals with functional rumen.
Do not use in animals with renal disease, including anuria and oliguria.

6. ADVERSE REACTIONS

In very rare cases the following adverse reactions may appear:
Hypersensitivity reactions, which may occasionally be serious, may occur, the severity varying from skin rash to anaphylactic shock.
Gastrointestinal symptoms (vomiting, diarrhoea).
Secondary infections from non-sensitive microorganisms after prolonged use.

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

Pigs
Chicken (broiler), duck (duck broiler) and turkey (turkey for meat production)

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

For administration in drinking water. Clear and colourless liquid when in solution.
Medicated drinking water should be refreshed or replaced every 24 hours.
The uptake of medicated water depends on the clinical condition of the animals, the environment, the age and the kind of feed provided. In order to obtain the correct dosage, the concentration of active substance has to be adjusted accordingly.

Dosage and treatment regimen
Pigs: 20 mg of amoxicillin trihydrate – equivalent to 17.4 mg of amoxicillin/kg of body weight every 24 hours (corresponding to 40 mg product/kg bodyweight/day) for 4 days.
Broilers: 15 mg of amoxicillin trihydrate – equivalent to 13.1 mg of amoxicillin/kg of body weight every 24 hours (corresponding to 30 mg product/kg bodyweight/day) for 5 days.
Duck broilers: 20 mg of amoxicillin trihydrate – equivalent to 17.4 mg of amoxicillin/kg of body weight every 24 hours (corresponding to 40 mg product/kg bodyweight/day) for 3 days.
Turkeys for meat production: 15 to 20 mg of amoxicillin trihydrate – equivalent to 13.1 to 17.4 mg of amoxicillin/kg of body weight every 24 hours (corresponding to 30-40 mg product/kg bodyweight/day) for 5 days.

9. ADVICE ON CORRECT ADMINISTRATION

Use the following formula in order to calculate the quantity of the product (mg) that should be incorporated in the drinking water tank:

$$\frac{\text{Dose (mg product per kg body weight per day)} \times \text{mean body weight (kg) of animals to be treated}}{\text{mean daily water consumption (litre) per animal per day}} = \text{___ mg product per litre drinking water}$$

The product must first be diluted in a small quantity of water in order to obtain a stock solution which is either further diluted in the drinking water tank or introduced via a water proportioner pump. The concentrated solution should be stirred for at least 15 minutes to ensure that dissolution is complete. When using a proportioner, adjust the pump between 2 to 5% and adapt the volume of preparation accordingly. Considering the maximum solubility of the product (20 g/l), a dosing pump with a setting of 2% cannot be used for administering the product to turkeys or pigs.

The use of suitably calibrated weighing equipment for the administration of the calculated amount of the product is recommended.
To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.
Prepare the solution with fresh tap water immediately before use.
Water uptake should be monitored at frequent intervals during medication.
In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated.
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.

10. WITHDRAWAL PERIOD(S)

Meat and offal: Pigs: 6 days
Chickens: 1 day.
Turkeys: 5 days
Ducks: 9 days.
Not authorised for use in birds producing eggs for human consumption and within 4 weeks before onset of the laying period.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 25 ºC. Protect from light. Store in a dry place.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: For immediate use.
Shelf life after reconstitution in water according to directions: 24 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
The use of the product should be combined with good management practices, i.e. good hygiene, proper ventilation, no overstocking.
The uptake of medication by animals can be altered as a consequence of illness.
In case of insufficient uptake of water, animals should be treated parenterally.

Special precautions for use in animals:
Not effective against beta-lactamase producing organisms.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animals. 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 amoxicillin and may decrease the

effectiveness of treatment with other penicillins, due to the potential for crossresistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins and cephalosporins cause hypersensitivity reactions (allergy) following injection, inhalation, ingestion or contact with the skin. Cross hypersensitivity reactions are observed between cephalosporins and penicillins.
- Do not handle the product if you are allergic to penicillins and/or cephalosporins.
- Handle the product with care to avoid inhaling the powder, and contact with the skin and eyes while adding it to water, taking special precautions:
  • Take the necessary action to prevent the powder from spreading while the product is being added to drinking water.
  • Personal protective equipment consisting of either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143, gloves, overalls and approved goggles should be worn when handling the veterinary medicinal product.
  • Avoid contact with the skin and eyes. In case of contact, rinse with plenty of clean water.
  • Do not smoke, eat or drink while handling the product.
  • Wash hands after use.
- If symptoms appear following exposure, such as a skin rash, seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Use during pregnancy and lactation:
Laboratory studies in rats and mice have not produced any evidence of teratogenic, foetotoxic, maternotoxic effects.
The safety of the veterinary medicinal product has not been established during pregnancy or lactation in pigs; Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with neomycin since it blocks the absorption of oral penicillins.
Do not use together with bacteriostatic antibiotics, such as tetracyclines, macrolides, sulphonamides, as they can antagonise the bactericidal effect of penicillins.

Overdose (symptoms, emergency procedures, antidotes):
No other adverse reactions are known than those mentioned in section 6.
In case of overdose, the treatment should be symptomatic. No specific antidote is available.

Incompatibilities:
In the 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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist 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

June 2020

15. OTHER INFORMATION

Pack sizes: sachets of 100 g, 300 g, 400 g and 1 kg.
Not all pack sizes may be marketed.

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

Rhemox 500 mg/g powder for use in drinking water for pigs, chicken broilers, duck broilers and turkeys for meat production [AT, BE, BG, CY, CZ, DE, EL, ES, HU, IE, IT, NL, PT, RO, SI, SK, UK]
Rhemox 500 mg/g powder for use in drinking water for pigs, chickens, ducks and turkeys [PL]
Rhemox 435.6 mg/g powder for use in drinking water for pigs, chicken broilers, duck broilers and turkeys for meat production [FR]
Rhemox vet [DK, SE]
Rhemox vet 500 mg/g powder for use in drinking water [FI]
Amoxicillin trihydrate

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder:
Industrial Veterinaria S.A.
Esmeralda, 19
E-08950 Esplugues de Llobregat (Barcelona)
Spain

Manufacturer responsible for batch release:
aniMedica Herstellungs GmbH
Pappelstr. 7 72160 Horb a. N
Germany

2. Name of the veterinary medicinal product

Rhemox 500 mg/g powder for use in drinking water for pigs, chicken broilers, duck broilers and turkeys for meat production [AT, BE, BG, CY, CZ, DE, EL, ES, HU, IE, IT, NL, PT, RO, SI, SK, UK]

Rhemox 500 mg/g powder for use in drinking water for pigs, chickens, ducks and turkeys [PL]

Rhemox 435.6 mg/g powder for use in drinking water for pigs, chicken broilers, duck broilers and turkeys for meat production [FR]

Rhemox vet [DK, SE]

Rhemox vet 500 mg/g powder for use in drinking water [FI]

Amoxicillin trihydrate

3. Statement of the active substance(s) and other ingredient(s)

Each gram contains:

Active substance:
Amoxicillin trihydrate 500 mg
(Equivalent to 435.6 mg Amoxicillin)

"Only for France:"
Amoxicillin (as trihydrate) 435.6 mg
(Equivalent to 500 mg of Amoxicillin trihydrate)

Excipient:
Citric acid

Fine and homogeneous white or slightly creamy powder.

4. Pharmaceutical form

Powder for use in drinking water.

5. Package size

1 kg

6. Indication(s)

Pigs: Treatment of infections caused by strains of *Streptococcus suis* susceptible to amoxicillin.
Chicken broilers, duck broilers and turkeys for meat production: Treatment of pasteurellosis and colibacillosis caused by strains of *Pasteurella spp*. and *Escherichia coli* sensitive to amoxicillin.

7. Contraindications

Do not use in case of hypersensitivity to penicillins, to other beta-lactams or to the excipient.
Do not use orally in rabbits, guinea pigs, hamsters or other small herbivores, given that amoxicillin, as for all aminopenicillins, has deleterious effects on caecal bacteria.
Do not use in horse given that amoxicillin, as all aminopenicillins, has an important effect on caecal bacteria.
Do not use orally in animals with functional rumen.
Do not use in animals with renal disease, including anuria and oliguria.

8. Adverse reactions

In very rare cases the following adverse reactions may appear:
Hypersensitivity reactions, which may occasionally be serious, may occur, the severity varying from skin rash to anaphylactic shock.

Gastrointestinal symptoms (vomiting, diarrhoea).
Secondary infections from non-sensitive microorganisms after prolonged use.

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}.

9. Target species

Pigs
Chicken (broiler), duck (duck broiler) and turkey (turkey for meat production)

10. Dosage for each species, route(s) and method of administration

For administration in drinking water. Clear and colourless liquid when in solution.
Medicated drinking water should be refreshed or replaced every 24 hours.
The uptake of medicated water depends on the clinical condition of the animals, the environment, the age and the kind of feed provided. In order to obtain the correct dosage, the concentration of active substance has to be adjusted accordingly.

Dosage and treatment regimen
Pigs: 20 mg of amoxicillin trihydrate – equivalent to 17.4 mg of amoxicillin/kg of body weight every 24 hours (corresponding to 40 mg product/kg bodyweight/day) for 4 days.
Broilers: 15 mg of amoxicillin trihydrate – equivalent to 13.1 mg of amoxicillin/kg of body weight every 24 hours (corresponding to 30 mg product/kg bodyweight/day) for 5 days.
Duck broilers: 20 mg of amoxicillin trihydrate – equivalent to 17.4 mg of amoxicillin/kg of body weight every 24 hours (corresponding to 40 mg product/kg bodyweight/day) for 3 days.
Turkeys for meat production: 15 to 20 mg of amoxicillin trihydrate – equivalent to 13.1 to 17.4 mg of amoxicillin/kg of body weight every 24 hours (corresponding to 30-40 mg product/kg bodyweight/day) for 5 days.

11. Advice on correct administration

Use the following formula in order to calculate the quantity of the product (mg) that should be incorporated in the drinking water tank:

$$\frac{\text{Dose (mg product per kg body weight per day)} \times \text{mean body weight (kg) of animals to be treated}}{\text{mean daily water consumption (litre) per animal per day}} = \text{___ mg product per litre drinking water}$$

The product must first be diluted in a small quantity of water in order to obtain a stock solution which is either further diluted in the drinking water tank or introduced via a water proportioner pump. The concentrated solution should be stirred for at least 15 minutes to ensure that dissolution is complete. When using a proportioner, adjust the pump between 2 to 5% and adapt the volume of preparation accordingly. Considering the maximum solubility of the product (20 g/l), a dosing pump with a setting of 2% cannot be used for administering the product to turkeys or pigs.

The use of suitably calibrated weighing equipment for the administration of the calculated amount of the product is recommended.
To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.
Prepare the solution with fresh tap water immediately before use.
Water uptake should be monitored at frequent intervals during medication.
In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated.
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.

12. Withdrawal period

Meat and offal: Pigs: 6 days
Chickens: 1 day.
Turkeys: 5 days
Ducks: 9 days.
Not authorised for use in birds producing eggs for human consumption and within 4 weeks before onset of the laying period.

13. Special storage precautions

Store below 25 ºC. Protect from light. Store in a dry place.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

14. Special warning(s)

Special warnings for each target species:
The use of the product should be combined with good management practices, i.e. good hygiene, proper ventilation, no overstocking.
The uptake of medication by animals can be altered as a consequence of illness.
In case of insufficient uptake of water, animals should be treated parenterally.

Special precautions for use in animals:
Not effective against beta-lactamase producing organisms.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animals. 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 amoxicillin and may decrease the effectiveness of treatment with other penicillins, due to the potential for crossresistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins and cephalosporins cause hypersensitivity reactions (allergy) following injection, inhalation, ingestion or contact with the skin. Cross hypersensitivity reactions are observed between cephalosporins and penicillins.
- Do not handle the product if you are allergic to penicillins and/or cephalosporins.
- Handle the product with care to avoid inhaling the powder, and contact with the skin and eyes while adding it to water, taking special precautions:
  • Take the necessary action to prevent the powder from spreading while the product is being added to drinking water.
  • Personal protective equipment consisting of either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143, gloves, overalls and approved goggles should be worn when handling the veterinary medicinal product.
  • Avoid contact with the skin and eyes. In case of contact, rinse with plenty of clean water.
  • Do not smoke, eat or drink while handling the product.
  • Wash hands after use.
- If symptoms appear following exposure, such as a skin rash, seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Use during pregnancy and lactation:
Laboratory studies in rats and mice have not produced any evidence of teratogenic, foetotoxic, maternotoxic effects.
The safety of the veterinary medicinal product has not been established during pregnancy or lactation in pigs; Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with neomycin since it blocks the absorption of oral penicillins.
Do not use together with bacteriostatic antibiotics, such as tetracyclines, macrolides, sulphonamides, as they can antagonise the bactericidal effect of penicillins.

Overdose (symptoms, emergency procedures, antidotes):
No other adverse reactions are known than those mentioned in section 6.
In case of overdose, the treatment should be symptomatic. No specific antidote is available.

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

15. Special precautions for the disposal of unused product or waste materials, if any

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

16. Date on which the package leaflet was last approved

June 2020

17. Other information

Pack sizes: sachets of 1 kg.

18. 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.
Administration by a veterinary surgeon, or under their direct responsibility.

19. The words “Keep out of the sight and reach of children”

Keep out of the sight and reach of children.

20. Expiry date

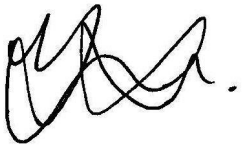
EXP
Shelf-life after first opening the container: For immediate use.
Shelf life after reconstitution in water according to directions: 24 hours.
Once broached, for immediate use

21. Marketing authorisation number(s)

Vm 36547/4005

22. Manufacturer's batch number

Batch



Approved: 29 September 2020