[Version 8, 10/2012]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DANIDOL 300 mg/ml Solution for use in drinking water for Cattle and Pigs (AT and DE)
EDERAL 300 mg/ml Solution for use in drinking water for Cattle and Pigs (only ES)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Ketoprofen 300 mg

Excipients:

Qualitative composition of excipients and other constituents
L-arginine
Citric acid anhydrous *for pH adjustment*
Purified water

Clear yellowish solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calf) and pigs (for fattening).

3.2 Indications for use for each the target species

Cattle (calf) and pigs (for fattening):
Treatment for the reduction of pyrexia and dyspnoea associated with respiratory disease in combination with anti-infective therapy, as appropriate.

3.3 Contraindications

Do not use in suckling calves.
Do not use in fasting animals or animals with limited access to feed.
Do not use in animals where there is the possibility of gastrointestinal alterations, ulceration or bleeding in order not to aggravate their situation.
Do not use in dehydrated or hypovolemic or hypotensive animal due to the potential risk of increased renal toxicity.
Do not use in swine fattened at extensive or semi-extensive production farms with access to soil or foreign objects that may damage the gastric mucosa, or with a high parasite burden, or under a severe stress situation.
Do not use in animals suffering from cardiac, hepatic, or renal disease. Do not use where there is evidence of blood dyscrasia.
Do not use in cases of hypersensitivity to ketoprofen or aspirin or to any of the excipients.

Do not use other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.
See also section 3.7

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

As ketoprofen may provoke gastrointestinal ulcerations, the use is not recommended in cases of PMWS (post-weaning multisystemic wasting syndrome) because ulcers are already frequently associated with this pathology.

To reduce the risk of adverse reactions do not exceed the recommended dose or duration of treatment.

When administering to pigs of less than 6 weeks of age or in aged animals it is necessary to adjust the dose accurately as well as to perform a close clinical follow-up.

To reduce the risk of ulceration treatment should be administered over 24 hours. For safety reasons the maximum treatment duration should not exceed 3 days. If side effects occur treatment must be stopped and the advice of a veterinarian should be sought. Treatment must be suspended for the whole group.

Water intake of treated animals should be monitored to ensure adequate intake. Individual animal medication, preferably by injection, will be required if daily water intake is insufficient.

Avoid use in dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.

This veterinary medicinal product does not contain any antimicrobial preservative.

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

The veterinary medicinal product may cause hypersensitivity reactions (skin rash, urticaria). People with known hypersensitivity to ketoprofen or any anti-inflammatory non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

Handle the veterinary medicinal product with care to avoid contact with skin and eyes while adding to the water. Personal protective equipment consisting of rubber gloves and safety glasses should be worn when handling the veterinary medicinal product.

In case of accidental spillage onto skin, the affected area should be rinsed immediately with water. In case of accidental eye contact, irrigate the eyes thoroughly with clean running water immediately. Seek medical advice if irritation persists.

Contaminated clothing should be removed and any splashes on to the skin should be washed off immediately.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs (for fattening):

Undetermined frequency (cannot be estimated from the available data)	Digestive tract disroder[1] Gastric ulceration[2] Soft stool[3]

[1] Superficial and Deep erosion of the gastrointestinal tract due to administration of ketoprofen at the recommended therapeutic dosage.
[2] Resulting in fatality, observed in black Iberian pigs, which have been related to being fattened at soil stations with a high parasite burden and the ingestion of foreign bodies
[3] Transitory, it disappears during or at the end of the treatment

Cattle (calf):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Adverse gastric reaction[1]
Undetermined frequency (cannot be estimated from the available data	Soft stool [2]

[1]Observed in weaning calves under severe stressful situations (transportation, dehydration, fasting, etc).
[2] Transitory, it disappears during or at the end of the treatment

If side effects occur treatment must be stopped for the whole group and the advice of a veterinarian should be sought.

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 systemhttps://www.ema.europa.eu/documents/template-form/qrd-appendix-i-adverse-event-phv-mss-reporting-details_en.docx. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Do not use during pregnancy in sows.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration of diuretics or potentially nephrotoxic drugs should be avoided since there is an increased risk of renal disturbances. This is secondary to the diminished blood flow caused by the inhibition of prostaglandins.
This veterinary medicinal product should not be administered concurrently with other NSAIDS or glucocorticosteroids due to the risk of exacerbating gastrointestinal ulceration.
Concurrent treatment with other anti-inflammatory substances may result in additional or increased adverse effects. A period of at least 24 hours should be observed between treatment with other anti-inflammatories and this product.
The treatment-free period should, however, take into account the pharmacological properties of the products used previously.

Anticoagulants, particularly coumarin derivatives such as warfarin, should not be used in combination with ketoprofen.
Ketoprofen is highly bound to plasma proteins. The concomitant administration of substances that are also highly plasma protein bound may compete with ketoprofen with the possibility of consequent toxic effects due to the unbound fraction of the drug.

3.9 Administration routes and dosage

In drinking water use:

Cattle (calf)
3 mg of ketoprofen/kg bw/d (equivalent to 1 ml/100 kg bw/d of the finished product)

Pigs (for fattening)
1.5 - 3 mg of ketoprofen/kg bw/d (equivalent to 0.5 - 1 ml/100 kg bw/d of the finished product). Dose of 1.5 mg/kg is effective in the treatment of mild to moderate processes (body temperature <41ºC). Dose must be increased up to 3mg of ketoprofen /kg bw to treat more severe cases.

Treatment should be given for one day. It can be continued for another 1-2 days after a risk/benefit assessment by the responsible veterinarian; see also 4.4 and 4.6.

Method of Administration:

The veterinary medicinal product is administered by the oral route, diluted in drinking water. Administration over a 24 hour period is recommended. Medicated water should be the only water supply during the period of treatment and should be refreshed every 24 hours. The product may be put directly into the header tank or introduced via a water proportioner pump. Once the treatment period has finished, the animals should be given unmedicated water.

The animals must have ad libitum access to food and medicated water before and during treatment. Start the treatment of recumbent animals with the parenteral form. To prevent overdosing, pigs should be grouped according to bodyweight and an average bodyweight estimated as accurately as possible.

The water intake of the animals to be treated should be measured before calculating the total amount of product to be administered each day. In order to calculate accurately the rate of incorporation of the product in drinking water, it is necessary to estimate the mean weight and the consumption of water of the animals to be treated, based on the average for the days immediately before treatment.

If it is administered by adding the product directly into the drinking water tank, this must contain enough water for the level of consumption that is anticipated for the following 24 hours. 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:

$$\text{ml veterinary medicinal product to be added to the water tank every 24h} = \frac{\text{Mean animal weight (kg) x number of animals to be treate} \quad \text{Dose (ml/100 kg)}}{100}$$

If the product is administered by a direct feeder into the water pipes, without first being diluted, the proper concentration of the product is obtained by applying the following formula:

$$\text{ml veterinary medicinal product/ L} = \frac{\text{Mean animal weight (kg) x Dose (ml/100 l}}{}$$

of drinking water = $\frac{\text{Mean daily water intake per animal (L) x 1}}{\text{}}$

If the content of the container is used in parts, to ensure a correct dosage, the use of the graduated dosing cup is necessary

In the case of prior dilution being necessary, the resulting concentration has to be duly adapted.

In order to ensure the consumption of the proper dosage throughout the whole of the treatment, it will be necessary to adjust the incorporation rate into the drinking water on a daily basis.

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

Overdose with NSAIDS can lead to gastro-intestinal ulceration, loss of proteins, hepatic and renal impairment. In tolerance studies performed with the product when administered in drinking water to cattle and pigs, up to 25% of the animals treated at five times the maximum recommended dose (15 mg/kg) for three days or at the recommended dose (3 mg/kg) for triple the maximum recommended time (9 days) showed gastric ulcerative lesions. Early signs of toxicity include loss of appetite and pasty faeces or diarrhoea. In case of overdosage, symptomatic treatment should be initiated. The occurrence of ulcers is dose dependent to a limited extent.

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 period(s)

Meat and offal: 1 day

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QM01 AE 03

4.2 Pharmacodynamics

Ketoprofen, 2-(phenyl 3-benzoyl) propionic acid is a non-steroidal anti-inflammatory drug belonging to the arylpropionic acid group. Ketoprofen inhibits the biosynthesis of prostaglandins (PGE2 and PGF2□) without affecting the ratio of PGE2/PGF2□ and thromboxanes. This mechanism of action results in its anti-inflammatory, anti-pyretic and analgesic activity. These properties are also attributed to its inhibiting effect on bradykinin and superoxide anions together with its stabilizing action on lysosomal membranes.
The antiinflammatory effect is enhanced by the conversion of the (R)-enantiomer to (S)-enantiomer. It is known that the (S)-enantiomer supports the ant-inflammatory effect of ketoprofen.

4.3 Pharmacokinetics

Following oral administration, ketoprofen is readily absorbed and binds strongly to plasma proteins. Ketoprofen is metabolised in the liver and converted into a carbonil-reduced derivation, the RP69400 metabolite.It is excreted primarily through the kidneys and, to a lesser extent, in the faeces.

Cattle (calf):
Following oral gavage administration at a dosage of 3 mg/kg to fattening calves, ketoprofen is absorbed readily (F=100%). Maximum concentrations (Cmax) of 3.7 µg/ml (2.5 to 4.5 µg/ml) are

achieved at 72 min (0.33 to 2h) after administration. (Tmax). Following absorption, the pharmacokinetics of ketoprofen are 7haracterized by a low volume of distribution (0.5 l/kg) and a short plasma elimination half-life (2.2 hours).

After repeated oral administration in drinking water in calves, the kinetic profile presents principally 2 different phases per administration day, clearly related to the day-night cycle, which influenced the animal's water consumption. The first phase (first 9 hours post-treatment) corresponded to the absorption phase of the product. Considering the rapid absorption phase for the single administration, the longer phase observed for repeated administrations is due to the administration route: ketoprofen administered via drinking water is consumed by the animals sparsely during the day. The elimination phase observed in the following hours is directly related to the low drinking water consumption by the animals during the night time. When administering the product at 3 mg ketoprofen/kg/d during 3 days in drinking water, the Cmax observed was 1.9 µg/ml (1.6 to 2.4 µg/ml) and Tmax was of 32h (9 to 57 h) after beginning of administrations.

Pigs (for fattening):
In swine, after oral gavage administration at a dosage of 3 mg ketoprofen/kg, a maximum mean concentration (Cmax) of 10.6 µg/ml (2.2 to 17.2 µg/ml) is attained, in average, at 60 min (0.33 to 2h) after administration (Tmax). Absolute bioavailability is high (84%). Volume of Distribution following IV administration is low (Vd=0.2 l/kg) and its elimination half-life is short (t1/2= 2.0h). Plasma clearance is 0.06 l/kg.h.

When administering the product at 3 mg ketoprofen/kg/d during 3 days in drinking water in pigs, the kinetic profile is similar to that of cattle. The Cmax observed was 2.7 µg/ml (1.4 to 4.2 µg/ml) and the Tmax was of 16h (6 to 57h) after beginning of administrations.

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: 5 years

Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution or reconstitution according to directions: 24 hours

5.3 Special precautions for storage

Keep the bottle tightly closed.

5.4 Nature and composition of immediate packaging

Nature of the container:

White high density polyethylene bottle with high density polyethylene screw cap (100 and 500 ml). A 30 ml graduated dosing is included.

Pack sizes:
Box containing 1 bottles of 100 ml + graduated dosing cup
Box containing 1 bottle of 500 ml + graduated dosing cup

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

Medicines should not be disposed of via wastewater or household waste.

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar Veterinaria S.L.U.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

16 December 2009

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

4. 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

4. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
100 ml
500 ml

4. NAME OF THE VETERINARY MEDICINAL PRODUCT

DANIDOL 300 mg/m Solution for use in drinking water for Cattle and Pigs (AT and DE)
EDERAL 300 mg/ml Solution for use in drinking water for Catlle and Pigs (only ES)

4. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Ketoprofen 300 mg

3. PACKAGE SIZE

100 ml.
500 ml.

4. TARGET SPECIES

Cattle (calf) and pigs (for fattening)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use, administer in drinking water.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 1 day

8. EXPIRY DATE

Exp {mm/yyyy}
Shelf life after first opening the container: 3 months
Shelf life after dilution: 24 hours
Once opened, used by….

9. SPECIAL STORAGE PRECAUTIONS

Keep the bottle tightly closed.

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

Ecuphar
An Animalcare Company

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
100 ml
500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DANIDOL 300 mg/ml Solution for use in drinking water for Cattle and Pigs (AT and DE)
EDERAL 300 mg/ml Solution for use in drinking water for Cattle and Pigs (only ES)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Ketoprofen 300 mg

3. TARGET SPECIES

Cattle (calf) and pigs (for fattening)

4. ROUTES OF ADMINISTRATION

Oral use, administer in drinking water.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 1 day

6. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the container: 3 months
Shelf life after dilution : 24 hours
Once opened, use by: ….

7. SPECIAL STORAGE PRECAUTIONS

Keep the bottle tightly closed.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar
An Animalcare Company

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

DANIDOL 300 mg/ml Solution for use in drinking water for Cattle and Pigs (AT and DE)
EDERAL 300 mg/ml Solution for use in drinking water for Cattle and Pigs (only ES)

2. Composition

Each ml contains:

Ketoprofen 300 mg

A clear yellowish solution.

3. Target species

Catlle (calf) and Pigs (for fattening).

4. Indications for use

Cattle (calf) and pigs (for fattening):
Treatment for the reduction of pyrexia and dyspnoea associated with respiratory disease in combination with anti-infective therapy, as appropriate.

5. Contraindications

Do not use in suckling calves.
Do not use in fasting animals or animals with limited access to feed
Do not use in animals where there is the possibility of gastrointestinal alterations, ulceration or bleeding in order not to aggravate their situation.
Do not use in dehydrated or hypovolemic or hypotensive animals due to the potential risk of increased renal toxicity.
Do not use in swine fattened at extensive or semi-extensive production farms with access to soil or foreign objects that may damage the gastric mucosa, or with a high parasite burden, or under a severe stress situation.
Do not use in animals suffering from cardiac, hepatic, or renal disease.
Do not use where there is evidence of blood dyscrasia.
Do not use in case of hypersensitivity to ketoprofen or aspirin or to any of the excipients.
Do not use other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.

6. Special warnings

Special precautions for safe use in the target species:

As ketoprofen may provoke gastrointestinal ulcerations, the use is not recommended in cases of PMWS (post-weaning multisystemic wasting syndrome) because ulcers are already frequently associated with this pathology.

To reduce the risk of adverse reactions do not exceed the recommended dose or duration of treatment.

When administering to pigs of less than 6 weeks of age or in aged animals it is necessary to adjust the dose accurately as well as to perform a close clinical follow-up.

To reduce the risk of ulceration treatment should be administered over 24 hours. For safety reasons the maximum treatment duration should not exceed 3 days. If side effects occur treatment must be stopped and the advice of a veterinarian should be sought. Treatment must be suspended for the whole group.

Water intake of treated animals should be monitored to ensure adequate intake. Individual animal medication, preferably by injection, will be required if daily water intake is insufficient.

Avoid use in dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.

This veterinary medicinal product does not contain any antimicrobial preservative.

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

The veterinary medicinal product may cause hypersensitivity reactions (skin rash, urticaria) could. People with known hypersensitivity to ketoprofen or any anti-inflammatory non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

Handle the veterinary medicinal product with care to avoid contact with skin and eyes while adding to the water. Personal protective equipment consisting of rubber gloves and safety glasses should be worn when handling the veterinary medicinal product.

In case of accidental spillage onto skin, the affected area should be rinsed immediately with water. In case of accidental eye contact, irrigate the eyes thoroughly with clean running water immediately. Seek medical advice if irritation persists.

Contaminated clothing should be removed and any splashes on to the skin should be washed off immediately.

Wash hands after use.

Pregnancy:

Do not use during pregnancy in sows.

Interaction with other medicinal products and other forms of interaction:

Concurrent administration of diuretics or potentially nephrotoxic drugs should be avoided since there is an increased risk of renal disturbances. This is secondary to the diminished blood flow caused by the inhibition of prostaglandins.
This veterinary medicinal product should not be administered concurrently with other NSAIDS or glucocorticosteroids due to the risk of exacerbating gastrointestinal ulceration.
Concurrent treatment with other anti-inflammatory substances may result in additional or increased adverse effects. A period of at least 24 hours should be observed between treatment with other anti-inflammatories and this product.
The treatment-free period should, however, take into account the pharmacological properties of the products used previously.
Anticoagulants, particularly coumarin derivatives such as warfarin, should not be used in combination with ketoprofen.

Ketoprofen is highly bound to plasma proteins. The concomitant administration of substances that are also highly plasma protein bound may compete with ketoprofen with the possibility of consequent toxic effects due to the unbound fraction of the drug.

Overdose:
Overdose with NSAIDS can lead to gastro-intestinal ulceration, loss of proteins, hepatic and renal impairment. In tolerance studies performed with the product when administered in drinking water to cattle and pigs, up to 25% of the animals treated at five times the maximum recommended dose (15 mg/kg) for three days or at the recommended dose (3 mg/kg) for triple the maximum recommended time (9 days) showed gastric ulcerative lesions. Early signs of toxicity include loss of appetite and pasty faeces or diarrhoea. In case of overdosage, symptomatic treatment should be initiated. The occurrence of ulcers is dose dependent to a limited extent.

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 (for fattening):

Undetermined frequency (cannot be estimated from the available data)	Digestive tract disorder[1] Gastric ulceration[2] Soft stool[3]

[1] Superficial and Deep erosion of the gastrointestinal tract due to administration of ketoprofen at the recommended therapeutic dosage.
[2] Resulting in fatality, observed in black Iberian pigs, which have been related to being fattened at soil stations with a high parasite burden and the ingestion of foreign bodies
[3] Transitory, it disappears during or at the end of the treatment

Cattle (calf):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Adverse gastric reaction[1]
Undetermined frequency (cannot estimated from the available data)	Soft stool[2]

[1] Observed in weaning calves under severe stressful situations (transportation, dehydration, fasting, etc).
[2] Transitory, it disappears during or at the end of the treatment

If side effects occur treatment must be stopped for the whole group and the advice of a veterinarian should be sought.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.
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 using the contact details at the end of this leaflet, or via your national reporting system.

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

In drinking water use:

Cattle (calf)
1 ml/100 kg bw/d of the Danidol 300 mg/ml oral solution (equivalent to 3 mg of ketoprofen/kg bw/d)

Pigs (for fattening)
0.5-1 ml/100 kg bw/d of the Danidol 300 mg/ml oral solution (equivalent to 1.5-3 mg of ketoprofen/kg bw/d)
Dose of 1.5 mg/kg is effective in the treatment of mild to moderate processes (body temperature <41ºC). Dose must be increased up to 3mg of ketoprofen /kg bw to treat more severe cases.

Treatment should be given for one day. It can be continued for another 1-2 days after a risk/benefit assessment by the responsible veterinarian; see also special warnings for each target species and adverse reactions.

Method of Administration:

The veterinary medicinal product is administered by the oral route, diluted in drinking water. Administration over a 24 hour period is recommended. Medicated water should be the only water supply during the period of treatment and should be refreshed every 24 hours. The product may be put directly into the header tank or introduced via a water proportioner pump. Once the treatment period has finished, the animals should be given unmedicated water.

The animals must have ad libitum access to food and medicated water before and during treatment. Start the treatment of recumbent animals with the parenteral form. To prevent overdosing, pigs should be grouped according to bodyweight and an average bodyweight estimated as accurately as possible.
The water intake of the animals to be treated should be measured before calculating the total amount of product to be administered each day. In order to calculate accurately the rate of incorporation of Danidol 300 mg/ml Oral Solution in drinking water, it is necessary to estimate the mean weight and the consumption of water of the animals to be treated, based on the average for the days immediately before treatment.

If it is administered by adding the product directly into the drinking water tank, this must contain enough water for the level of consumption that is anticipated for the following 24 hours. 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:

$$\text{ml veterinary medicinal product to be added to the water tank every 24 h} = \frac{\text{Mean animal weight (Kg)} \times \text{number of animals to be treated} \times \text{Dose (ml/100 kg)}}{100}$$

If the product is administered by a direct feeder into the water pipes, without first being diluted, the proper concentration of the product is obtained by applying the following formula:

$$\text{ml veterinary medicinal product /L of drinking water} = \frac{\text{Mean animal weight (Kg)} \times \text{Dose (ml/100 kg)}}{\text{Mean daily water intake per animal (L)} \times 100}$$

If the content of the container is used in parts, to ensure a correct dosage, the use of the graduated dosing cup is necessary .

In the case of prior dilution being necessary, the resulting concentration has to be duly adapted.

In order to ensure the consumption of the proper dosage throughout the whole of the treatment, it will be necessary to adjust the incorporation rate into the drinking water on a daily basis.

9. Advice on correct administration

Water intake of treated animals should be monitored to ensure adequate intake. Individual animal medication, preferably by injection, will be required if daily water intake is insufficient.

10. Withdrawal periods

Meat and offal: 1 day

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the bottle tightly closed.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. 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 according to directions: 24 hours

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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

Pack sizes:
Box containing 1 bottle of 100 ml + graduated dosing cup
Box containing 1 bottle of 500 ml + graduated dosing cup

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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 and contact details to report suspected adverse reactions:
Ecuphar Veterinaria S.L.U.
C/Cerdanya, 10-12 Planta 6º
08173 Sant Cugat del Vallés
Barcelona
Spain
Tel.: +34 935 95 50 00
E-mail: info@ecuphar.com

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodón s/n, Finca La Riba, Vall de Bianya
17813 Gerona (Spain)

17. Other information