[Version 8, 10/2012]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DINALGEN 60 mg/ml solution for injection for pigs (all countries except DK, SE and FI)
DINALGEN (DK)
DINALGEN VET (SE and FI)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance	
Ketoprofen	60 mg
Excipients	
Benzyl alcohol (E1519)	10 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

Clear colourless solution

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

Pigs:
Reduction of pyrexia in cases of respiratory disease and Postpartum Dysglactia Syndrome/Mastitis, Metritis, Agalactiae (MMA syndrome) in sows, in combination with anti-infective therapy, as appropriate.

4.3 Contraindications

Do not use in animals where there is the possibility of gastro-intestinal ulceration or bleeding, in order not to aggravate their situation.
Do not use in animals suffering from cardiac, hepatic, or renal disease.

Do not use in dehydrated or hypovolemic or hypotensive animals due to the potential risk of increased renal toxicity.
Do not use in case of hypersensitivity to ketoprofen or aspirin or to any of the excipients.
Do not use where there is evidence of blood dyscrasia or blood coagulation disturbances.
Do not use other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.
See also section 4.7

4.4 Special warnings for each target species

None..

4.5 Special precautions for use

Special precautions for use in animals
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.
Since gastric ulceration is a common finding in PMWS (Post-weaning Multisystemic Wasting Syndrome), the use of ketoprofen in pigs affected by this pathology is not recommended, in order not to aggravate their situation.
Avoid use in dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.
Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid contact with the skin, eyes and mucous membranes.
In case of accidental skin, eye or mucous membrane contact, irrigate the affected area thoroughly with clean running water immediately. Seek medical advice if irritation persists.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.
Hypersensitivity reactions (skin rash, urticaria) could occur. People with known hypersensitivity to the active substance should avoid contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Intramuscular injection may be followed by transient irritation at the injection site.
The administration of ketoprofen in pigs at the recommended therapeutic dosage may cause superficial erosion and/or superficial ulceration of the gastrointestinal tract.
If side effects occur treatment must be stopped and the advice of a veterinarian should be sought.

4.7 Use during pregnancy, lactation or lay

The safety of ketoprofen has been investigated in pregnant laboratory animals (rats, mice, rabbits) and cattle. No adverse effects were noted. As the safety of ketoprofen has not been assessed in pregnant sows, the product should be used in this case only according to the benefit/risk assessment by the responsible veterinarian.

4.8 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 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 and may compete with other highly bound drugs which can lead to toxic effects.

4.9 Amounts to be administered and administration route

Intramuscular use.
3 mg ketoprofen/kg bw, i.e. 1ml of product per 20 kg bw, administered once by deep intramuscular injection.
Depending on the response observed and based on the benefit-risk analysis by the responsible veterinarian treatment may be repeated at intervals of 24 hours for a maximum of three treatments. Each injection should be given at a different site.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdose with NSAIDS can lead to gastro-intestinal ulceration, loss of proteins, hepatic and renal impairment. In tolerance studies performed in pigs with the product up to 25% of the animals treated at three times the maximum recommended dose (9 mg/kg) for three days or at the recommended dose (3 mg/kg) for triple the maximum recommended time (9 days) showed erosive and/or ulcerative lesions in both the aglandular (*pars oesophagica*) and glandular parts of the stomach. Early signs of toxicity include loss of appetite and pasty faeces or diarrhoea. If overdose symptoms are observed, symptomatic treatment should be initiated. The occurrence of ulcers is dose dependent to a limited extent.

4.11 Withdrawal period(s)

Meat & offal: 3 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and Antirheumatic Products, Non-Steroids, Propionic acid derivatives,
ATCvet code: QM01 AE 03

5.1 Pharmacodynamic properties

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 PGF2α) without affecting the ratio of PGE2/PGF2α 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.

5.2 Pharmacokinetic particulars

After intramuscular administration ketoprofen is rapidly absorbed, having a high bioavailability and binding extensively to plasma proteins (>90%). Its elimination from plasma is rapid, although in the inflammatory exudate, it is more persistent. Ketoprofen is metabolized in liver and it is excreted mainly in urine and, to a lesser extent, in faeces.

In pigs, following the intramuscular injection of a single dose of 3 mg/ketoprofen/kg bw, the active drug substance is rapidly absorbed, reaching its average Cmax in plasma (13 μg/ml) between 0,5 and 1 hour (Tmax) after initiation of the treatment. The bioavailability is high, of approximately 96%. Mean distribution volume is low (Vd=0.2 l/kg), and the average elimination half-life is short (T1/2=2 h).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
L-arginine
Citric acid anhydrous for pH adjustment
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other substances in the same syringe.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years
Shelf-life after first opening the immediate packaging: 28 days

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Nature of the container:
Amber type II glass vials, closed with bromobutyl rubber stoppers and flip-off aluminium caps (100 ml) or aluminium caps (250 ml).

Presentations:
Vial containing 100 ml
Vial containing 250 ml
10 x vial containing 100 ml
10 x vial containing 250 ml

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ecuphar veterinaria S.L.U.
C/Cerdanya, 10-12 Planta 6º
08173 Sant Cugat del Vallés
Barcelona (Spain)

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

October 2008

10. DATE OF REVISION OF THE TEXT

02/2022

PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only. To be supplied only on veterinary prescription.