PACKAGE LEAFLET

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

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

Marketing authorisation holder:

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

Manufacturer for the batch release:
Pfizer Olot, S.L.U.
Ctra. Camprodón s/n, Finca La Riba, Vall de Bianya
17813 Gerona (Spain)

2. 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)
Ketoprofen

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

Each ml contains:

Ketoprofen	60 mg
Benzyl alcohol (E1519)	10 mg

A clear colourless solution.

4. INDICATION(S)

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.

5. 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.

6. ADVERSE REACTIONS

lntramuscular injection may be followed by transient irritation at the injection site.
The administration of ketoprofen in pigs at the recommended therapeutic dose 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.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs.

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

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, treatment may be repeated at intervals of 24 hours for a maximum of three treatments, at the discretion of the attending veterinarian. Each injection should be given at a different site.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Meat and offal: 3 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions
Shelf life after first opening the inmediate packaging: 28 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after "EXP"

12. SPECIAL WARNING(S)

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.

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.

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.

Overdose (symptoms, emergency procedures, antidotes)

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.

Incompatibilities

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

02/2022

15. OTHER INFORMATION

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.

When the vial is broached for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
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