B. PACKAGE LEAFLET

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DANIDOL 300 mg/ml Oral Solution for Cattle and Pigs (AT, DE, FR, UK)

EDERAL 300 mg/ml Oral Solution for Cattle and Pigs (only ES)

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

DANIDOL 300 mg/ml Oral Solution for Cattle and Pigs (AT, DE, FR, UK)
EDERAL 300 mg/ml Oral Solution for Cattle and Pigs (only ES)

Ketoprofen

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

Each ml contains 300 mg of Ketoprofen as active substance.
A clear yellowish solution.

4. INDICATION(S)

Fattening Cattle and Pigs:
Treatment for the reduction of pyrexia and dyspnoea associated with respiratory disease in combination with anti-infective therapy, as appropriate.

5. CONTRAINDICATIONS

Do not administer to suckling calves.
Do not administer to 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 administer to 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. ADVERSE REACTIONS

The administration of ketoprofen in pigs at the recommended therapeutic dosage may cause superficial and deep erosion of the gastrointestinal tract.

Serious adverse reactions of a gastric nature have very rarely been observed in weaning calves under severe stressful situations (transportation, dehydration, fasting, etc). Cases of gastric ulceration resulting in fatality have been 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. Other cases in intensive farming have been related to forced fasting situations prior or during treatment.

Transitory softening of faeces may occur which, in any event, 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.

7. TARGET SPECIES

Fattening Cattle and Pigs.

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

Oral use:

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

Pigs
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. Add the quantity of product that results from the following formula to the tank:

$$\text{ml DANIDOL 300 mg/ml Oral Sol. to be added to the water tank every 24 h} = \frac{\text{Mean animal weight (Kg) x number of animals to be treated x Dose (ml/100 kg)}}{100}$$

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:

$$\text{ml DANIDOL 300 mg/ml Oral Sol. /L of drinking water} = \frac{\text{Mean animal weight (Kg) x Dose (ml/100 kg)}}{\text{Mean daily water intake per animal (L) x 100}}$$

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 PERIOD

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".
Shelf-life after first opening the immediate packaging: 3 months
Shelf-life after reconstitution in drinking water: 24 hours

12. SPECIAL WARNING(S)

Special precautions for use in animals
As ketoprofen may provoke gastrointestinal ulcerations, the use is not recommended in case 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
Personal protective equipment consisting of rubber gloves and safety glasses should be worn when mixing 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. 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
Do not use in pregnant 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 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 (symptoms, emergency procedures, antidotes)

Overdose with NSAIDS can lead to gastro-intestinal ulceration, loss of proteins, hepatic and renal impairment. In tolerance studies performed with Danidol 300 mg/ml oral solution in 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.

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

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

Bottles of 100 ml and 500 ml.
Includes a 30 ml graduated dosing cup for precise dose adjustment
Not all pack sizes may be marketed.

When the bottle is opened 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.