LABEL/PACKAGE LEAFLET FOR:

KETOXYME 100mg/ml
Solution for use in drinking water

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

2.

Marketing authorisation holder:
Andersen, S.A.
Avda. de la Llana, 123
08191 Rubí (SPAIN)

Manufacturer responsible for batch release:
Labiana Life Sciences, S.A.
C/ Venus, 26
08228 Terrassa (SPAIN)

3. NAME OF THE VETERINARY MEDICINAL PRODUCT

4.

KETOXYME 100 mg/ml Solution for use in drinking water
Ketoprofen

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

Each ml contains:
Active substance:

Ketoprofen		100 mg

Excipients:

Benzyl alcohol	(E1519)	20 mg
Excipients qst		1 ml

Clear and colourless solution.

4. INDICATIONS

Symptomatic treatment for reduction of pyrexia associated with infectious respiratory diseases in pigs in combination with an appropriate anti-infective therapy, as appropriate.

5. CONTRAINDICATIONS

Do not use where there is evidence of blood dyscrasia. 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 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.

6. ADVERSE REACTIONS

Using the veterinary medicinal product according with the proposed posology:

- In very rare occasions gastric symptoms (as gastritis, gastric erosion and gastric ulceration) may occur. Where administration is performed over a 24 hour period, no severe ulcers were identified.
- In very rare occasions the feed intake may decrease.

In tolerance studies, in which the treatment was carried out during 3 to 9 days, ulcers have been observed in very common occasions. It is recommended that the veterinary medicinal product is administered in accordance with the proposed posology to decrease the incidence of gastric ulcerations.

It is recommended that the daily dose is administered over a period of 24 hours. The total daily dose should not be administered over a shorter period than recommended as this has been shown to result in more severe gastric ulceration.

Three days after the cessation of dosing, gastric ulcers generally recover (with some residual scarring) or are in the process of recovery/cicatrisation.
If serious adverse events such as signs of ulcers or gastrointestinal haemorrhage occur, use of the product should be stopped and the advice of a veterinarian should be sought.
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

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

The veterinary medicinal product is administered by the oral route, diluted in drinking water at a dose of 3 mg of ketoprofen/kg bodyweight/day (equivalent to 0.3 ml of veterinary medicinal product/10 kg b.w./day). Based on the benefit-risk assessment of the veterinarian, additional administration for another 1-2 days at the most can be considered.
Administration over a 24 hour period is recommended.

The following calculation should be made to determine the quantity of product to be added in drinking water daily:

$$\frac{\text{0.03 ml veterinary medicinal product / kg b.w. / day} \times \text{Average body weight (kg)}}{\text{Average amount of drinking water (L/animal)}} = \text{Total volume (ml)/L of drinking water/day}$$

9. ADVICE ON CORRECT ADMINISTRATION

Medicated water should be refreshed every 24 hours.
The water intake of the pigs to be treated should be measured before calculating the total amount of product to be administered each day.
The product may be put directly into the header tank or introduced via a water proportioner pump.
Medicated water should be the only water supply during the period of treatment.
To prevent overdosing, pigs should be grouped according to bodyweight and an average bodyweight estimated as accurately as possible."

10. WITHDRAWAL PERIOD

Meat and offal: 2 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.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
Shelf life after first opening the container: 4 months.
Shelf life after dilution according to directions: 24 hours.

12. SPECIAL WARNINGS

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

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.
Avoid use in animals with hypoproteinemia due to the increased risk of toxicity caused by the highly plasma protein bound nature of ketoprofen, which may result in toxic effects due to the unbound fraction of the drug.
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.

Special precautions to be taken by the person administering the veterinary medicinal product People with known hypersensitivity to ketoprofen or benzyl alcohol should avoid the contact with the veterinary medicinal product.
Personal protective equipment consisting of impenetrable gloves and safety glasses should be worn when mixing the veterinary medicinal product.
In the case of accidental spillage onto skin, the affected area should be washed immediately with soap and water.
In case of accidental eye contact, flush the eyes thoroughly with clean running water immediately. Seek medical advice if irritation persists.
Hypersensitivity reactions (skin rash, urticaria) could occur. If irritation persists and you develop such symptoms following exposure, you should seek medical advice and show the label or package leaflet to the physician. Swelling of the face, lips, or eyes or difficulty breathing, are more serious symptoms and require urgent medical attention.
Contaminated clothing should be removed immediately.
Wash hands after use.

Pregnancy and lactation
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. The use is not recommended during pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction
Do not administer in combination with anticoagulants, particularly coumarin derivatives such as warfarin.
Concomitant administration of other drugs have to be assessed by the veterinarian responsible.
Do not administer corticosteroids or other NSAIDs concurrently or within 24 hours of each other.
Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given non-steroidal anti-inflammatory drugs.
The concomitant administration of active substances that are highly plasma protein bound may demonstrate a competitive effect with the ketoprofen with the possibility of consequent toxic effects due to the unbound fraction of the drug.

Concurrent use with diuretics or potentially nephrotoxic drugs has a higher risk to develop renal disturbances secondary to the diminishing blood flow caused by the inhibition of prostaglandins.

Overdose (symptoms, emergency procedures, antidotes)
Overdose up to 3x the recommended dose can cause gastrointestinal ulcers, protein loss, and kidney and liver damage. Early signs of toxicity include loss of appetite and depression. In case of overdosage, symptomatic treatment should be initiated.

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 product should be disposed of in accordance with local requirements.

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.

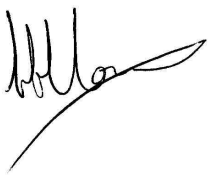
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

21 May 2019

15. OTHER INFORMATION

Pack size: 1L bottle provided with a polypropylene cup measuring device graduated from 10 to 75 ml.
For animal treatment only.
To be supplied only on veterinary prescription
Once opened use by …
Batch
EXP

Vm 39897/4001



Approved 02 July 2019