B. PACKAGE LEAFLET

PACKAGE LEAFLET:

ALGENAMIC 40 mg/ml solution for injection

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

Marketing authorisation holder:
VETPHARMA ANIMAL HEALTH, S.L.
Gran Via Carles III, 98, 7ª
08028 Barcelona
Spain

Manufacturer responsible for batch release:
MEVET S.A.U.
Polígono Industrial El Segre, p. 409-410,
25191 Lleida
Spain

Distributed by

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALGENAMIC 40 mg/ml solution for injection
Tolfenamic acid

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substances:
Tolfenamic acid……. 40.0 mg

Excipients:
Benzyl alcohol (E 1519) …….. 10.4 mg
Sodium formaldehyde sulfoxylate…… 5.0 mg

Clear, yellowish solution, free from visible particles.

4. INDICATIONS

Cattle:
- As an adjunct in the reduction of acute inflammation associated with respiratory diseases.
- As an adjunct in the treatment of acute mastitis.

Pigs:
- As an adjunct in the treatment of Metritis Mastitis Agalactia syndrome.

Cats:
- As an adjunct in the treatment of upper respiratory disease in association with antimicrobial therapy, if appropriate.

Dogs:
- For the treatment of inflammatory and painful postoperative syndromes.
- For the reduction of postoperative pain.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any excipient.
Do not use in animals with cardiac disease, impaired hepatic function or acute renal insufficiency.
Do not use in case of ulceration or digestive bleeding or in case of blood dyscrasia.
Do not inject intramuscularly in cats.

6. ADVERSE REACTIONS

Rarely, calves may collapse after rapid intravenous injection. When administered intravenously, the product should be injected slowly. After the first signs of intolerance appear, stop the injection.

Anorexia, vomiting, diarrhoea or blood in stools may occur in dogs and cats.
Polyuria and polydipsia may occur transiently. In most cases, these symptoms usually disappear spontaneously upon suppression of treatment.

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

Cattle, pigs, dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Cattle: Intramuscular (IM) and intravenous (IV).
Pigs: Intramuscular (IM).
Dogs: Intramuscular and subcutaneous.
Cats: Subcutaneous (SC).

<u>Cattle:</u>
- As an adjunct in the reduction of acute inflammation associated with respiratory diseases: 2 injections of 2 mg of tolfenamic acid/kg b.w. (equivalent to 1 ml of the

product/20 kg b.w. each one), by IM route in the neck muscles, separate by 48 hours. Do not exceed 20 ml per injection site.
- As an adjunct in the treatment of acute mastitis: 4 mg of tolfenamic acid / kg b.w. (equivalent to 1 ml of the product/10 kg b.w.) by IV route, in a single dose.

Pigs:
- As an adjunct in the treatment of Metritis Mastitis Agalactia syndrome: 2 mg of tolfenamic acid /kg b.w. (equivalent to 1 ml of the product/20 kg b.w.), by IM route in the neck muscles, in a single dose. Do not exceed 20 ml per injection site.

Dogs:
- For the treatment of inflammatory and painful postoperative syndromes: 4 mg of tolfenamic acid/kg b.w. (equivalent to 1 ml of the product/10 kg b.w.) by IM or SC route. This dose can be repeated after 24 hours.
- For the reduction of postoperative pain in dogs: 4 mg of tolfenamic acid/kg b.w. (equivalent to 1 ml of the product/10 kg b.w.), by IM route, in a single dose, one hour before induction to anaesthesia.

Cats:
- As an adjunct in the treatment of upper respiratory disease in association with antimicrobial therapy, if appropriate: 4 mg of tolfenamic acid/kg b.w. (equivalent to 1 ml of the product /10 kg b.w.), by SC route. This dose can be repeated after 24 hours. Do not use IM route in cats.

In animals of reduced weight, it is advisable to use insulin-type syringes to ensure a correct dosage.

9. ADVICE ON CORRECT ADMINISTRATION

The stopper may be safely punctured up to 50 times for the 250 mL vials, and 25 times for the 20 mL and 100 mL vials. The user should choose the most appropriate vial size according to the target species to be treated.

10. WITHDRAWAL PERIOD(S)

Cattle:
Intramuscular use:
Meat and offal: 12 days
Milk: zero hours

Intravenous use:
Meat and offal: 4 days
Milk: 24 hours

Pigs:
Meat and offal: 16 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 and carton after “EXP”. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days.

12. SPECIAL WARNINGS

Special warnings for use in animals:

Use in animals less than 6 weeks of age, or in aged animals, may involve additional risk. If such a use cannot be avoided animals may require a reduced dosage and careful clinical management is essential. Reduced metabolism and excretion in these animals should be considered.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.
Concurrent administration of potential nephrotoxic drugs should be avoided.
It is preferable that the product is not administered to animals undergoing general anaesthesia until fully recovered.
In case of undesirable effects (anorexia, vomiting, diarrhoea, presence of blood in faeces) occurring during the treatment, your veterinarian should be contacted for advice and the possibility of stopping treatment should be considered.
In dogs, the scale of pain relief after pre-operative administration may be influenced by the severity and duration of the operation.

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

The product may cause skin sensitisation. People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) or to benzyl alcohol should avoid contact with the veterinary medicinal product.
Administer the veterinary medicinal product with caution to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
This product may cause skin and eye irritation. Avoid contact with skin or eyes. In case of accidental contact, wash immediately exposed area with plenty of clean water.

Pregnancy and lactation

Cats and dogs:
The safety of the veterinary medicinal product has not been established in cats and dogs during pregnancy and lactation.
The use is not recommended during pregnancy or lactation.

Cattle and pigs:
The results of the studies carried out in the rat and in the rabbit showed no teratogenic effect.
Peri and postnatal studies performed in the rat showed that tolfenamic acid has no influence on the evolution of viability, the gestation index or the appearance of malformations.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Do not administer with other non-steroidal anti-inflammatory drugs simultaneously or with an interval of 24 hours between them. Other NSAIDs, diuretics, anticoagulants and substances with high affinity to plasma proteins may compete for binding and produce toxic effects.
Do not administer in conjunction with anticoagulants.
Avoid simultaneous administration of potentially nephrotoxic drugs.
Do not administer in conjunction with glucocorticoids.

Overdose (symptoms, emergency procedures, antidotes):

The studies of tolerance in bovines allowed to define that a dose 4 times superior to the therapeutic one (16 mg / kg b.w.) can constitute the margin of safety of administration of the product.
At doses of 18 and 20 mg / kg b.w. (4.5 and 5 times the therapeutic dose), signs of toxicity were recorded transiently at the central level, in the form of agitation, balance disorders and motor incoordination.
There were significant variations in the hematological and biochemical parameters that corresponded to transient modifications of the digestive and hepatic functions.
In pigs, tolfenamic acid is well tolerated (up to 5 times higher than the therapeutic dose), although there may initially be reactions at the injection site that are intense and of spontaneous recovery in 7-14 days.

In case of overdosage in dogs and cats, the symptoms described in the section on adverse reactions may appear exacerbated. In this case it is recommended to suspend the treatment and establish a symptomatic treatment.

Incompatibilities:

In the absence of compatibility studies this veterinary medicinal product should 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:
Cardboard box with 1 glass vial of 20 ml
Cardboard box with 1 glass vial of 100 ml
Cardboard box with 1 glass vial of 250 ml

Cardboard box with 5 glass vials of 20 ml
Cardboard box with 10 glass vials of 100 ml
Cardboard box with 15 glass vials of 250 ml
Not all pack sizes may be marketed.

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