



TOLFEDOL 40 mg/ml

solution for injection for cattle, pigs, cats and dogs

COMPOSITION PER ML

Tolfenamic acid 40 mg

TARGET SPECIES AND INDICATIONS

Cattle: Adjunct treatment of pneumonia, TOLFEDOL improves the general conditions and nasal discharge. Adjunct treatment of acute mastitis.

Pigs: Adjunct treatment of Metritis Mastitis Agalactia.

Dogs: Treatment of inflammation associated with musculo-skeletal disorders and the reduction of post-operative pain.

Cats: Adjunct treatment of upper respiratory disease in association with antimicrobial therapy, if appropriate.

SPECIAL PRECAUTIONS 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 cats undergoing general anaesthesia until fully recovered. Do not exceed the prescribed dosage or duration of treatment. The scale of pain relief after pre-operative administration may be influenced by the severity and duration of the operation. Animals suffering from a chronic renal insufficiency and requiring an anti-inflammatory treatment may be treated with tolfenamic acid without requiring an adjustment of the dosage. However, the use of this product is contra-indicated in acute cases of renal insufficiency. 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.

DOSAGE AND METHOD OF ADMINISTRATION

Cattle: For inflammation associated with respiratory disease in cattle, the recommended dosage is 2 mg/kg (1 ml/20 kg bodyweight) by intramuscular injection into the neck area. Treatment may be repeated once after 48 hours. For use in mastitis, the recommended dosage is 4 mg/kg bodyweight (1ml per 10 kg bodyweight) as a single IV injection.

Pigs: the recommended dosage is 2 mg/kg (1ml/20kg bodyweight) as a single intramuscular injection.

Cats and dogs: The recommended dose is 4 mg/kg bodyweight (1 ml/10 kg bodyweight) given as a single injection and repeated once after 24 to 48 hours if required and depending upon clinical assessment. Alternatively, a single injection of 1 ml/10 kg can be given with, the treatment being continued by the oral route, using tablets. In dogs administer by intramuscular or subcutaneous injection. For the reduction of post-operative pain, this is best given pre-operatively, at the time of premedication one hour before induction of anaesthesia. In cats, administer by the subcutaneous route only.

Do not exceed 20 ml per injection site.

WITHDRAWAL PERIOD

Cattle: Intramuscular injection. Meat and offal: 12 days. Milk: zero hours
Intravenous injection. Meat and offal: 4 days. Milk: 24 hours.

Pigs: Meat and offal: 16 days.

Presentations: 20 ml, 50 ml, 100 ml, 250 ml. Not all pack sizes may be marketed.

Marketing Authorization: 3279 ESP / DE, IE, FR, PT, DE, RO, SK

Whilst the information contained in this leaflet has been reviewed by our Technical staff, it is intended to complement the advice of the veterinary professional. For full SPC contact with our local distributor or ask for advice through our website www.spveterinaria.com



TOLFEDOL

40 mg/ml



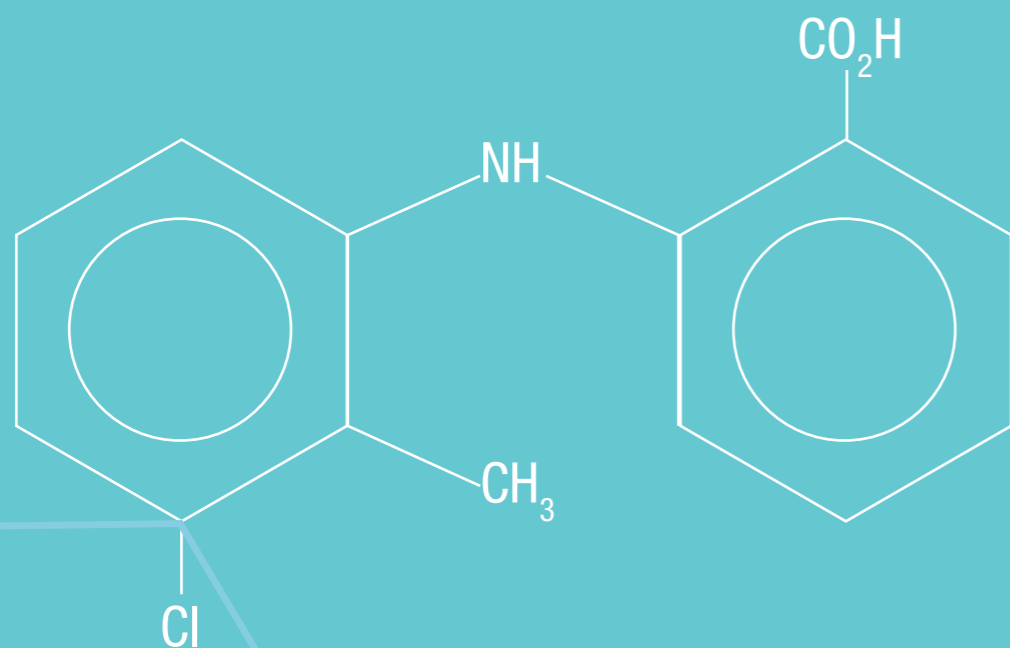
QUICK and CONVINCING

- ✓ Anti inflammatory
- ✓ Anti pyretic
- ✓ Analgesic



TOLFEDOL

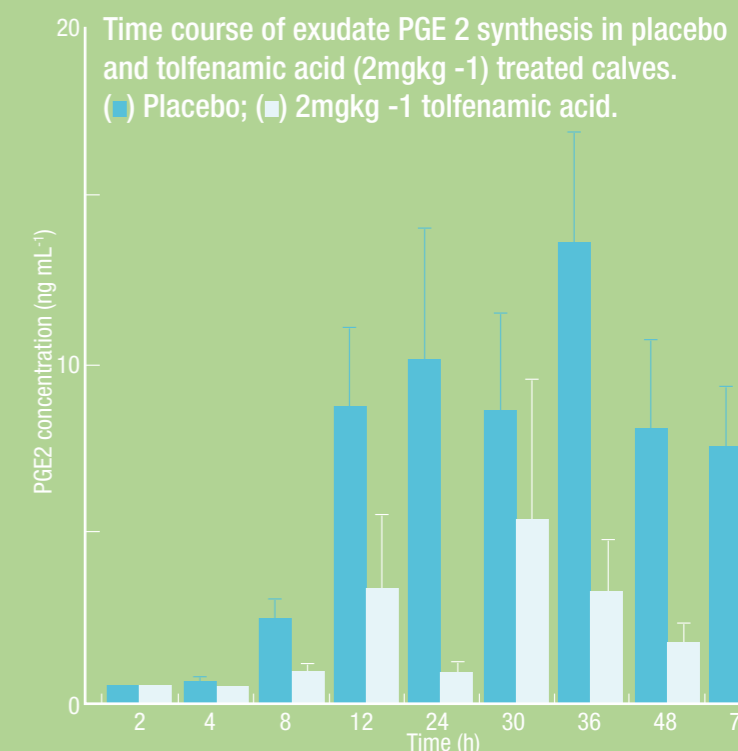
TOLFENAMIC ACID 40 mg/ml



PROLONGED ANTI INFLAMMATORY ACTIVITY



Following tolfenamic acid administration, concentrations of PGE 2 were significantly reduced at all sampling times up to 72h. (Lees et al, 1998)



1 Target-effective

Anti inflammatory activity on different levels:

- Inhibition of PGE2 synthesis
 - Inhibition of Leukotriene synthesis
 - Inhibition of Beta-glucuronidase
 - Reduction of TXB2 serum concentration
 - Inhibition of Bradykinin -mediated inflammation
 - Reduction of oedematous response
- (Lees et al, 1998), (Landoni et al, 1996)

TOLFENAMIC ACID penetrates and diffuses fast into the inflammatory exudate, reaching higher concentrations than in plasma.



2 Safe and protective

- ✓ Not teratogenic nor embryotoxic
- ✓ No mutagenic effects
- ✓ No peri- or postnatal toxicity
- ✓ No effects on fertility
- ✓ **Low gastro-ulcerogenic potency**

Relative GI ulcerogenic potency:

• Tolfenamic acid.....	1
• Indomethacin.....	6.6
• Acetylsalicylic acid	18.2
• Naproxene	73.9
• Ketoprofen.....	75.3

(Eskerod, 1994; Corell, 1994)



3 Powerful

Taking the inhibitory effect of O₂⁻ (superoxide anions) generation as a study parameter, it is shown that 0,01 µg/ml **TOLFENAMIC ACID** has the same effect compared to 0,1 µg/ml **Flunixin** or 1,0 µg/ml **Ketoprofene**. (Landoni et al, 1995)

A SINGLE IV INJECTION of Tolfenamic acid is EQUIVALENT to 3 IV INJECTIONS of Flunixin meglumine and Ketoprofen, showing better clinical results with Tolfenamic acid. (Woehrlé et al, 2002).

TOLFEDOL = **Ketoprofen**

