PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfine, 4% solution for injection for cattle and pigs
Tolfenamic acid, nonsteroidal anti-inflammatory, analgesic, antipyretic solution for injection I.M. in pigs I.V. & S.C in cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Amber glass vials of 50ml 100ml sterile aqueous solution containing 4.0% w/v tolfenamic acid as active ingredient, 1.04% w/v benzyl alcohol and 0.50 % w/v sodium formaldehyde sulphoxylate as preservatives.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50ml
100ml

5. TARGET SPECIES

Cattle - Pigs

6. INDICATION(S)

Tolfine is an anti-inflammatory, antipyretic and analgesic

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Tolfine is an anti-inflammatory, antipyretic and analgesic agent indicated:

Species	Indication	Route	Dose	Withdrawal Periods
Pig	Metritis mastitis aga-lactia syndrome used in conjunction with antibacterial therapy	IM***	2mg/kg bw 1ml/20kg	Meat: 3 days
Cattle	Acute mastitis used in conjunction with anti-bacterial therapy	IV	4mg/kg bw 1ml/10kg	Meat: 3 days Milk: 24 hours**
	Respiratory disease used in conjunction with antibacterial therapy	IV	2mg/kg bw 1ml/20kg*	Meat: 3 days Milk: 24 hours**
		SC	2mg/kg bw 1ml/20kg*	Meat: 7 days Milk: not for use in dairy cattle

*may be repeated once after 48 hours. If a second injection is needed this should be given in the opposite side of the animal's body.
**milk from treated cattle must only be used for human consumption after 24 hours i.e. at the second milking. Milk from the first milking after treatment should be discarded.
*** in neck musculature

8. WITHDRAWAL

Withdrawal Periods
Meat: 3 days
Meat: 3 days Milk: 24 hours**
Meat: 3 days Milk: 24 hours**
Meat: 7 days Milk: not for use in dairy cattle

9. SPECIAL WARNING(S), IF NECESSARY

See package leaflet. Take care to avoid self-injection. In case of eye or skin contact wash immediately with water.
Following withdrawal of the first dose, the product should be used within 28 days.

10. EXPIRY DATE

Exp.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only

POM-V

To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder
Vetoquinol UK Ltd
Vetoquinol House
Great Slade
Buckingham Industrial Park
Buckingham
MK18 1PA

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4063

17. MANUFACTURER'S BATCH NUMBER

Lot.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfine, 4% solution for injection for cattle and pigs
Tolfenamic acid, Non-steroidal anti-inflammatory, Analgesic, Antipyretic, solution for injection I.M. in pigs I.V. and S.C. in cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Amber glass vials of 50ml 100ml sterile aqueous solution containing 4.0% w/v tolfenamic acid as active ingredient, 1.04% w/v benzyl alcohol and 0.50% w/v sodium formaldehyde sulphoxylate as preservatives.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50ml
100ml

5. TARGET SPECIES

Cattle – Pigs

6. INDICATIONS

Tolfine is an anti-inflammatory, antipyretic and analgesic agent

7. METHOD AND ROUTE OF ADMINISTRATION

Tolfine is an anti-inflammatory, antipyretic and analgesic agent indicated:

Species	Indication	Route	Dose	Withdrawal Periods
Pig	Metritis mastitis aga-lactia syndrome used in conjunction with antibacterial therapy	IM	2mg/kg bw 1ml/20kg	Meat: 3 days
Cattle	Acute mastitis used in conjunction with anti-bacterial therapy	IV	4mg/kg bw 1ml/10kg	Meat: 3 days Milk: 24 hours**
	Respiratory disease used in conjunction with antibacterial therapy	IV	2mg/kg bw 1ml/20kg*	Meat: 3 days Milk: 24 hours**
		SC	2mg/kg bw 1ml/20kg*	Meat: 7 days Milk: not for use in dairy cattle

*may be repeated once after 48 hours. If a second injection is needed this should be given in the opposite side of the animal's body. **milk from treated cattle must only be used for human consumption after 24 hours i.e. at the second milking. Milk from the first milking after treatment should be discarded.
*** in neck musculature

8. SPECIAL WARNINGS, IF NECESSARY

See package leaflet. Following withdrawal of the first dose, the product should be used within 28 days. Keep the container in the outer carton.
Once broached, use by:

9. EXPIRY DATE

Exp.:

10. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.

11. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

To be supplied only on Veterinary Prescription
POM-V

13. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:
Vetoquinol UK Ltd
Vetoquinol House
Great Slade
Buckingham Industrial Park
Buckingham
MK18 1PA

15. MARKETING AUTHORISATION NUMBER

Vm 08007/4063

16. MANUFACTURER'S BATCH NUMBER

Lot.

PACKAGE LEAFLET FOR:

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

Marketing authorisation holder
Vetoquinol UK Ltd
Vetoquinol House
Great Slade
Buckingham Industrial Park
Buckingham
MK18 1PA

Site of batch release
Vetoquinol SA
Magny-Vernois, 70200 Lure
FRANCE
And
Vetoquinol Biowet Sp. z o.o.
13/14 Kosynierów Gdyńskich Str.
66-400 Gorzów Wlkp.
POLAND

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfine, 4% solution for injection for cattle and pigs

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

Amber glass vials of 50 ml or 100ml sterile aqueous solution containing 4.0% w/v tolfenamic acid as active ingredient, 1.04% w/v benzyl alcohol and 0.50 % w/v sodium formaldehyde sulphoxylate as preservatives.

4. INDICATION(S)

Tolfine is an anti-inflammatory, antipyretic and analgesic agent indicated:

Species	Indication	Route	Dose	Withdrawal Periods
Pig	Metritis mastitis agalactia syndrome used in conjunction with antibacterial therapy	IM***	2mg/kg bw 1ml/20kg	Meat: 3 days
Cattle	Acute mastitis used in conjunction with antibacterial therapy	IV	4mg/kg bw; 1ml/10kg	Meat: 3 days Milk: 24 hours**
	Respiratory disease used in conjunction with antibacterial therapy	IV	2mg/kg bw; 1ml/20kg*	Meat: 3 days Milk: 24 hours**
		SC	2mg/kg bw; 1ml/20kg*	Meat: 7 days Milk: **not for use in dairy cattle**

**may be repeated once after 48 hours. If a second injection is needed this should be given in the opposite side of the animal's body.*

***milk from treated cattle must only be used for human consumption after 24 hours i.e. at the second milking. Milk from the first milking after treatment should be discarded*

****in neck musculature*

5. CONTRAINDICATIONS

Not for IM administration in cattle
Not for IV or SC administration in pigs
Not for SC administration in dairy cows

6. ADVERSE REACTIONS

Transient swelling and inflammation can occur at the injection site.

7. TARGET SPECIES

Cattle - Pig

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

See section 4.

9. ADVICE ON CORRECT ADMINISTRATION

See section 4.

10. WITHDRAWAL PERIOD(S)

See section 4.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach of children.

Do not store above 25°C. Protect from light. Following withdrawal of the first dose, the product should be used within 28 days.

When the vial is opened for the first time, using the in use shelf life of 28 days, the date on which any product remaining in the container to be discarded should be worked out. This discard date should be written in the space provided on the label.

Keep the container in the outer carton.

12. SPECIAL WARNING(S)

Warnings

- Do not exceed 20 ml per intramuscular injection site.

- Do not exceed the stated dose or duration of treatment.

- use aseptic precautions when administering the product.

- When treating a number of animals the use of a draw-off needle is recommended to avoid excessive broaching of the closure.

- Use is contra-indicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, or where there is evidence of hypersensitivity to the product.

- Do not administer other NSAIDS concurrently or within 24 hours of each other. Tolfenamic acid is highly bound to plasma proteins and may compete with other highly bound drugs which can lead to toxic effects.

- Use in any animal less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided animals may require a reduced dosage and careful clinical management.

- avoid use in any dehydrated, hypovolaemic or hypotensive animal as there is a potential risk of increased renal toxicity.

- It is preferable that a NSAID which inhibits prostaglandin synthesis is not administered to animals undergoing general anaesthesia until fully recovered.

- Concurrent administration of potentially nephrotoxic drugs should be avoided.

- The product may be used during lactation. As there are limited data to support use during pregnancy, use of the product in pregnant animals should be at the discretion of the veterinary surgeon after the risks and benefits have been considered.

User precautions

- take care to avoid self-injection. In case of eye or skin contact, wash immediately with water.

For animal treatment only

To be supplied only on veterinary prescription

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

http://www.vmd.defra.gov.uk/ProductInformationDatabase/Default.aspx

15. OTHER INFORMATION

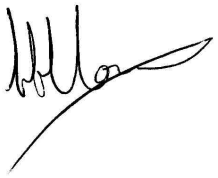
Pharmacological properties
Tolfenamic acid (n-(2-methyl-3-chlorophenyl) anthranilic acid) is a non-steroidal anti-inflammatory drug (nsaid) belonging to the fenamate group. Tolfenamic acid exerts anti-inflammatory, analgesic and antipyretic activities. The anti-inflammatory activity of tolfenamic acid is mainly due to an inhibition of cyclo-oxygenase and thus to a reduction in the synthesis of prostaglandins and thromboxanes, which are important inflammatory mediators.

Pharmacokinetic properties
Pigs
In pigs, tolfenamic acid injected by im route at a dose of 2mg/kg is rapidly absorbed from the injection site with a mean maximum plasma concentration of about 2.3ug/ml obtained at about 1 hour. The volume of distribution is approximately 1.3 l/kg in pigs. It is extensively bound to plasma albumin (>97%). Tolfenamic acid distribution involves extracellular fluids where concentrations similar to plasma are achieved both in healthy and inflamed peripheral tissues. Tolfenamic acid undergoes extensive enterohepatic recirculation and, as a result, prolonged concentrations are found in plasma. The elimination half-life varies from 3 - 5 hours in pigs.
In pigs, tolfenamic acid is eliminated mainly unchanged in faeces (~30%) and urine (~70%).
Cattle
Tolfenamic acid is distributed in all the organs with a high concentration in the plasma, digestive tract, liver, lungs and kidneys. However, the concentration in the brain is low. Tolfenamic acid and its metabolites do not cross the placental barrier to

any great extent.tolfenamic acid distribution involves extracellular fluids where concentrations similar to plasma are achieved both in healthy and inflamed peripheral tissues. It also appears in milk in the active form, mainly associated with the curds. Tolfenamic acid undergoes extensive enterohepatic recirculation and, as a result, prolonged concentrations are found in plasma. The elimination half-life varies from 8 - 15 hours in cattle. In cattle, tolfenamic acid is eliminated mainly unchanged in faeces (~30%) and urine (~70%).

Vm 08007/4063

POM-V



Approved 23 March 2017