

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALGENAMIC 40 mg/ml solution for injection
Tolfenamic acid

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Tolfenamic acid..... 40.0 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

20 ml
100 ml
250 ml
5 x 20 ml
10 x 100 ml
15 x 250 ml

5. TARGET SPECIES

Cattle, pigs, dogs and cats

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

Cattle: IM and IV
Pigs: IM
Dogs: IM and SC
Cats: SC
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:

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

9. SPECIAL WARNINGS, IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

Once opened, use by...

Shelf life after first opening the container: 28 days

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

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

For animal treatment only. 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

VETPHARMA ANIMAL HEALTH, S.L.

Gran Via Carles III, 98, 7^a

08028 Barcelona

Spain

Distributed by:

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL – VIAL OF 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALGENAMIC 40 mg/ml solution for injection
Tolfenamic acid

2. QUANTITY OF THE ACTIVE SUBSTANCE

Tolfenamic acid..... 40.0 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

4. ROUTES OF ADMINISTRATION

Intramuscular, intravenous or subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

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

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP {month/year}

Once opened, use by...
Shelf life after first opening the container: 28 days

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL – VIAL OF 100 ml AND 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALGENAMIC 40 mg/ml solution for injection
Tolfenamic acid

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Tolfenamic acid..... 40.0 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs, dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular, intravenous or subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use by:
Shelf life after first opening the container: 28 days.

11. SPECIAL STORAGE CONDITIONS

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

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

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VETPHARMA ANIMAL HEALTH, S.L.
Gran Via Carles III, 98, 7^a
08028 Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Batch {number}