LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 50 ml, 100 ml or 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Allevinix 50 mg/ml solution for injection for cattle, pigs and horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:

Flunixin ..... (as meglumine)	50	mg

Excipients:

Phenol	5	mg
Sodium formaldehyde sulfoxylate.....	2.5	mg
Disodium edetate.....	0.1	mg

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle, pigs and horses

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Cattle/pigs: Intramuscular
Cattle/horses: Intravenous

7. WITHDRAWAL PERIODS

Cattle:
Meat and offal: 10 days (IV route) / 31 days (IM route).
Milk: 24 hours (IV route) / 36 hours (IM route).
Pigs:
Meat and offal: 20 days.
Horses:
Meat and offal: 10 days.
Milk: the product is not authorised for use in lactating animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {MM/YYYY} Once broached use by __/__/__

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25^0 C after first opening the immediate packaging.

Keep the vial in the outer carton

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

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

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

14. MARKETING AUTHORISATION NUMBER

Vm 15052/5042

15. BATCH NUMBER

Lot{number}

16. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label of 100 ml or 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Allevinix 50 mg/ml solution for injection for cattle, pigs and horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:		
Flunixin	50	mg
(as meglumine)		
Excipients:		
Phenol	5	mg
Sodium formaldehyde sulfoxylate.....	2.5	mg
Disodium edetate.....	0.1	mg

3. TARGET SPECIES

Cattle, pigs and horses.

4. ROUTES OF ADMINISTRATION

Cattle/pigs: IM.
Cattle/horses: IV.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Cattle:
Meat and offal: 10 days (IV route) / 31 days (IM route).
Milk: 24 hours (IV route) / 36 hours (IM route).
Pigs:
Meat and offal: 20 days.
Horses:
Meat and offal: 10 days.
Milk: the product is not authorised for use in lactating animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {MM/YYYY}.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C after first opening the immediate packaging. Keep the vial in the outer carton.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

9. BATCH NUMBER

Lot{number}

10. PACKAGE SIZE

100 ml
250 ml

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: read package leaflet.

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

POM-V To be supplied only on veterinary prescription

15. MARKETING AUTHORISATION NUMBER

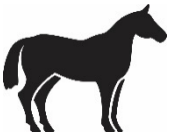
Vm 15052/5042

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Allevinix



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Flunixin: 50 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {MM/YYYY}

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

50ml

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

B. PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Allevinix 50 mg/ml solution for injection for cattle, pigs and horses

2. COMPOSITION

Each ml contains:

Active substance:		
Flunixin	50	mg
(as meglumine)		
Excipients:		
Phenol	5	mg
Sodium formaldehyde sulfoxylate.....	2.5	mg
Disodium edetate.....	0.1	mg

Colourless to pale yellow solution, clear and practically free from particles

3. TARGET SPECIES

Cattle, pigs and horses.

4. INDICATIONS FOR USE

Cattle:

Alleviation of clinical signs of respiratory disease when used concurrently with appropriate anti-infective therapy.

Pigs:

To support appropriate antibiotic therapy in the treatment of Mastitis-Metritis-Agalactia syndrome.

Alleviation of fever associated with respiratory disease when used in conjunction with specific antibiotic therapy.

Horses:

Alleviation of inflammation and pain associated with musculo-skeletal disorders.

Alleviation of visceral pain associated with colic.

5. CONTRAINDICATIONS

Do not use in animals suffering from chronic musculo-skeletal disorders.
Do not use in animals suffering from cardiac, hepatic or renal disease.
Do not use in animals with gastro-intestinal lesions (gastro-intestinal ulceration or bleeding).

Do not use in case of haemorrhagic disorders.
Do not use in case of hypersensitivity to flunixine meglumine, other NSAIDs or any of the excipients.

Do not use in animals suffering from colic caused by ileus and associated with dehydration.

Do not use the product within 48 hours before expected parturition in cows. In such cases an increase in the number of stillbirths has been observed.
Do not exceed the stated dose or the duration of treatment.

6. SPECIAL WARNING(S)

Special warnings

The underlying cause of the inflammatory condition or colic must be determined and treated appropriate concomitant therapy.

Special precautions for safe use in the target species

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

It is preferable that NSAIDs which inhibit prostaglandin synthesis are not administered to animals undergoing general anaesthesia until fully recovered.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal except in the case of endotoxaemia or septic shock.

In rare cases, shock (potentially fatal), may occur after intravenous injection, due to a high quantity of propylene glycol in the medicinal product. The product must be injected slowly and at body temperature. Stop injection at the first signs of intolerance and treat for shock if necessary.

Due to its anti-inflammatory properties, flunixin may mask clinical signs and therefore possible resistance to antibiotic treatment.

NSAIDs are known to have the potential to delay parturition through a tocolytic effect by inhibiting prostaglandins that are important in signalling the initiation of parturition. The use of the product in the immediate post-partum period may interfere with uterine involution and expulsion of fetal membranes resulting in retained placentae. See also section "Pregnancy and lactation".

Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

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

Flunixin meglumine is a non-steroidal anti-inflammatory drug (NSAID). The product may cause an allergic reaction in people sensitised to NSAIDs. People with known hypersensitivity to NSAIDs should avoid contact with the product.

Hypersensitivity reactions may be serious.

This product may cause skin and eye irritation.

Avoid contact with skin or eyes.

In case of skin contact, wash exposed area with soap and plenty of water. If symptoms persist, seek medical advice.

In case of contact with the eyes, wash eyes thoroughly with clean water and seek medical advice.

Avoid risk of ingestion, do not eat or drink when using the veterinary medicinal product and wash hands after use. In case of ingestion of the veterinary medicinal product seek medical advice.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Pregnancy and lactation

Studies in laboratory animals have produced evidence of foetotoxicity from flunixin after oral administration (rabbit and rat) and intramuscular administration (rat) at maternotoxic doses as well as an increase in the gestation period (rat).
The safety of flunixin has not been assessed in pregnant mares, breeding stallions and bulls. Do not use in these animals.
The safety of flunixin was demonstrated in pregnant cows and sows, as well as boars. The product may be used in these animals except within the 48 hours preceding parturition (see sections "Contraindications" and "Adverse events").
The product should only be administered within the first 36 hours post-partum following a benefit/risk assessment performed by the responsible veterinarian, and treated animals should be monitored for retained placentae.

Interaction with other medicinal products and other forms of interaction

Do not administer other NSAIDs concurrently or within 24 hours of each other, as it may increase the toxicity, mainly gastro-intestinal, even with low doses of acetylsalicylic acid.
The concurrent administration of corticoids may increase toxicity of the two products and increase the risk of gastro-intestinal ulceration. It should therefore be avoided.

Flunixin may reduce the effect of some anti-hypertensive medicinal products, such as diuretics, Angiotensin Conversion Enzyme (ACE) inhibitors, and beta blockers, by inhibition of prostaglandin synthesis.
Concurrent administration of potentially nephrotoxic drugs, particularly aminoglycosides, should be avoided.
Flunixin may reduce renal elimination of some drugs and increase their toxicity, such as aminoglycosides for example.

Overdose
Overdose is associated with gastrointestinal toxicity. Signs of ataxia and incoordination may also appear.
In horses, following 3 times the recommended dose (3 mg/kg bodyweight) administered by intravenous injection, a transient increase in blood pressure may be observed.
In cattle, administration of 3 times the recommended dose (6 mg/kg bodyweight) by intravenous injection did not induce untoward effects.
In pigs, following a dose of 2 mg flunixin/kg, administered twice a day, painful reactions at the injection site and an increase in the number of leucocytes was reported.

Major incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. ADVERSE EVENTS

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	Collapse NOS*, Death* Anaphylaxis
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastric ulceration NOS, Gastric irritation, Vomiting Renal disorder NOS** Injection site reaction NOS

* Mainly during rapid intravenous injection.
** In dehydrated or hypovolaemic animals

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Collapse NOS*, Death* Anaphylaxis
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastric ulceration NOS, Gastric irritation, Vomiting, Blood in faeces NOS, Diarrhoea Renal disorder NOS**

Mainly during rapid intravenous injection.

In dehydrated or hypovolaemic animals

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastric ulceration NOS, Gastric irritation, Vomiting Renal disorder NOS **

In dehydrated or hypovolaemic animals

As with other non-steroidal anti-inflammatory drugs, idiosyncratic renal or hepatic untoward effects may be observed.

The product may delay parturition and increase stillbirths through a tocolytic effect by inhibiting prostaglandins that are important in signalling the initiation of parturition. The use of the product in the immediate post-partum period may result in retained placentae.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

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

Cattle and pigs: Intramuscular use.
Cattle and horses: Intravenous use.
The body weight should be accurately determined before the administration.

Cattle:
2 mg of flunixin per kg bodyweight, equivalent to 2 ml of solution per 50 kg bodyweight, administered once daily by intravenous or intramuscular injection for 1 to 3 consecutive days.
Volumes greater than 20 ml should be divided and administered at least at 2 different injection sites.

Pigs:
To support appropriate antibiotic therapy in the treatment of Mastitis-Metritis-Agalactia syndrome:

2 mg of flunixin per kg bodyweight, equivalent to 2 ml of solution per 50 kg bodyweight, administered once daily by intramuscular injection for 1 to 3 consecutive days.

Alleviation of fever associated with respiratory diseases:

2 mg of flunixin per kg bodyweight, equivalent to 2 ml of solution per 50 kg bodyweight, administered once daily by intramuscular injection.

Maximum dosage volume per injection site should not exceed 5 ml. Volumes greater than 5 ml should be divided and administered at different injection sites.

Horses:
Alleviation of inflammation and pain associated with musculo-skeletal disorders:

1 mg of flunixin per kg bodyweight, equivalent to 1 ml of solution per 50 kg bodyweight, administered once daily by intravenous injection for 1 to 5 consecutive days.

Alleviation of visceral pain associated with colic:

1 mg of flunixin per kg bodyweight, equivalent to 1 ml of solution per 50 kg bodyweight, administered once daily by intravenous injection. Treatment may be repeated once or twice if colic recurs.

9. ADVICE ON CORRECT ADMINISTRATION

The cap can be broached up to 10 times. When treating large groups of animals at one time, use an automatic dosing device.

10. WITHDRAWAL PERIOD(S)

Cattle:
Meat and offal: 10 days (IV route) / 31 days (IM route).
Milk: 24 hours (IV route) / 36 hours (IM route).
Pigs:
Meat and offal: 20 days.
Horses:
Meat and offal: 10 days.
Milk: the product is not authorised for use in lactating animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C after first opening the immediate packaging.

Do not use this veterinary medicinal product after the expiry date stated on the label or carton after EXP. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 28 days.

Once the immediate package is opened, using the shelf-life after first opening, calculate the discard date and record in the space provided.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V To be supplied only on veterinary prescription

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 15052/5042

Cardboard box of 1 glass vial of 50 ml, 100 ml or 250 ml
Cardboard box of 1 plastic vial of 50 ml, 100 ml or 250 ml
Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

July 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:

Ceva Santé Animale
10, av. de la Ballastière
33500 Libourne
France

or

Vetem S.p.A.
Lungomare L. Pirandello 8,
92014 Porto Empedocle (AG)
Italy

17. OTHER INFORMATION

Environmental properties Flunixin is toxic to avian scavengers although foreseen low exposure leads to low risk.

Approved 12 March 2024