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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 50 mg of flunixin (as meglumine)

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle, pigs and horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle/pigs: Intramuscular use
Cattle/horses: Intravenous use

7. WITHDRAWAL PERIODS

Withdrawal period:
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 veterinary medicinal product is not authorised for use in lactating animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

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

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 OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBER

Vm 15052/3010

15. BATCH NUMBER

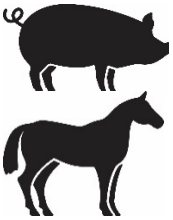
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Allevinix (UK(NI))



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

Flunixin 50 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 50 mg of Flunixin (as meglumine).

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

Withdrawal period:

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 veterinary medicinal product is not authorised for use in lactating animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

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 veterinary medicinal 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 warnings

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 veterinary medicinal product. The veterinary medicinal 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 signaling the initiation of parturition. The use of the veterinary medicinal 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 veterinary medicinal product may cause an allergic reaction in people sensitised to NSAIDs. People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

Hypersensitivity reactions may be serious.
This veterinary medicinal 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 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 veterinary medicinal product may be used in these animals except within the 48 hours preceding parturition (see sections "Contraindications" and "Adverse events").

The veterinary medicinal 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):	Anaphylaxis (with collapse)[1] Death[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Bleeding[2], gastrointestinal irritation[2], gastric ulceration[2] Renal damage[2] Injection site reaction[3]
Undetermined frequency (cannot be estimated from the available data)	Renal and hepatic disorders[4] Delayed parturition[5], increase of stillbirths[5], retained placenta[6]

[1]mainly during rapid intravenous injection
[2] mainly in dehydrated or hypovolaemic animals
[3] following intramuscular injection
[4] idiosyncratic effects
[5] through a tocolytic effect by inhibiting prostaglandins that are important in signalling the initiation of parturition
[6] in cases of the use of the veterinary medicinal product in the immediate post-partum period

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylaxis (with collapse)[1] Death[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Bleeding[2], gastrointestinal irritation[2], gastric ulceration[2], blood in faeces, diarrhea (liquid) Renal damage[2]
Undetermined frequency (cannot be estimated from the available data)	Renal and hepatic disorders[3] Delayed parturition[4], increase of stillbirths[4], retained placenta[5]

[1]mainly during rapid intravenous injection
[2] mainly in dehydrated or hypovolaemic animals
[3] idiosyncratic effects
[4] through a tocolytic effect by inhibiting prostaglandins that are important in signalling the initiation of parturition
[5] in cases of the use of the veterinary medicinal product in the immediate post-partum period

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Bleeding[1], gastrointestinal irritation[1], gastric ulceration[1], vomiting[1] Renal damage[1]
Undetermined frequency (cannot be estimated from the available data)	Renal and hepatic disorders[2] Delayed parturition[3], increase of stillbirths[3], retained placenta[4]

[1] mainly in dehydrated or hypovolaemic animals
[2] idiosyncratic effects
[3] through a tocolytic effect by inhibiting prostaglandins that are important in signalling the initiation of parturition
[4] in cases of the use of the veterinary medicinal product in the immediate post-partum period

In case of untowards effects stop treatment and seek medical advice.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Cattle: Intramuscular and intravenous uses.
Pigs: intramuscular use
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 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.

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 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. Treatment may be repeated once or twice if colic recurs.

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

9. Advice on correct administration

10. 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 veterinary medicinal 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.

12. Special precautions for disposal

Medicines should not be disposed of via waste water or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems.

These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorization numbers and pack sizes

Vm 15052/3010

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

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

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