ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Flunixin 50 mg
(as equivalent 83mg of Flunixin Meglumine)

Excipients:
Phenol 5.0 mg
Sodium Formaldehyde sulfoxylate 2.5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injections.
Clear, colorless to yellowish solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horse and pig.

4.2 Indications for use, specifying the target species

Horses: for the alleviation of inflammation and pain associated with musculo-skeletal disorders. For the alleviation of visceral pain associated with colic in the horse.
Cattle: temperature reduction in acute inflammatory processes of the respiratory tract and as adjunctive therapy in the treatment of acute mastitis.
Pigs: adjunctive therapy in MMA syndrome in sows.

4.3 Contraindications

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 with haemorrhagic diathesis.
Do not use in animals with known hypersensitivity to the active substance and any of excipients.
Do not use the product within 48 hours before expected parturition in cows.
Do not use in pregnant mares.
Do not use in pregnant sows.
Do not use in sows and gilts prior to mating and in breeding boars.
Do not use in case of evidence of blood dyscrasia.
Do not use in animals suffering from iliac colic or colic associated with dehydration

4.4 Special warnings for each target species

Do not exceed the recommended dose and duration of treatment.

4.5 Special precautions for use

Special precautions for use in animals

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 foetal membranes resulting in retained placentae. See also section 4.7.

Application of the product to animals younger than six weeks old and to old animals may involve additional risk. If such use cannot be avoided animals may require reduction of the dose and additional clinical monitoring.

Intravenous administration should be performed slowly and at body temperature to prevent shock reactions. At the first signs of incompatibility the administration must be suspended and if necessary the anti-shock treatment must be started immediately. Since flunixin meglumine can reduce clinical manifestations as a function of its anti-inflammatory activity, for example resistance to causal antibiotic therapy can be masked. Ponies may be more sensitive to adverse reactions caused by NSAIDs and therefore in these animals the product should be used with caution. In horses the cause of colic must be well determined and treated with adequate concomitant therapy.

Do not administer intra-arterially. Horses during intra-arterial administration may experience reactions such as ataxia, dyspnoea, cramps, etc., which disappear after a few minutes.

Do not apply to hypovolemic animals except those that are affected by endotoxemia or septic shock.

Administration of NSAIDs, which inhibit prostaglandin synthesis, is not recommended in animals under general anesthesia and until it is completely resolved.

Do not apply to the fat tissue.

Do not use in piglets weighing less than 6 kg.

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

The non-steroidal anti-inflammatory products may cause reactions in sensitive individuals. People with known hypersensitivity to active substance or to any of the excipients should avoid contact with the veterinary medicinal product. Hypersensitivity reactions may be serious.

This product may cause skin and eye irritation. Avoid contact with skin or eyes.

In case of accidental contact with skin or eyes, rinse immediately with plenty of water and seek medical advice.

Avoid risk of ingestion. Do not eat, drink or smoke while handling the product. In case of ingestion of the product seek medical advice.

Avoid accidental self-injection. 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.

4.6 Adverse reactions (frequency and seriousness)

Flunixin meglumine is a NSAID. This group of products is associated with a risk of gastrointestinal irritation and ulcers. Administration to animals with dehydration, hypovolaemia is associated with the risk of renal failure. In pigs and horses, administration of the product may cause local irritation at the injection site. Adverse reactions may occur as a consequence of the concomitant administration of other medicinal products (see section 4.8)

4.7 Use during pregnancy, lactation

Safety studies showed that the product may be used in pregnant and lactating cattle.
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.
Do not use in pregnant mares and sows. The safety studies in pregnant mares and sows have not been conducted.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer other NSAIDs in the next 24 hours. Some NSAIDs may be highly bind to plasma proteins and compete with other highly bind substances, which can lead to toxic effects. Simultaneous application of other potentially nephrotoxic products is not recommended. Flunixin may reduce the effect of some antihypertensive medicinal products by inhibiting prostaglandin synthesis, such as diuretics, ACE inhibitors, angiotensin II receptor antagonists (ARAs) and beta-blockers. Moreover it can reduce the renal elimination of some medicines, increasing their toxicity as it does with aminoglycosides.

4.9 Amounts to be administered and administration route

For intravenous (cattle, horses) and intramuscular (pigs) injection.

Cattle
2.2mg flunixin per kg bodyweight (equivalent to 2ml of product per 45kg BW) intravenously once a day, for up to 3 consecutive days. Must determine the cause of acute inflammatory process and start appropriate therapy.

Horses
Musculoskeletal disorders:
1.1mg flunixin per kg bodyweight (equivalent to 1ml of product per 45kg BW) intravenously once a day, up to 5 consecutive days according to clinical response.
Colic:
1.1mg flunixin per kg bodyweight (equivalent to 1ml of product per 45kg BW) intravenously. Pain alleviation usually occurs within 15 minutes. The administration can be repeated once or twice if colic recurs. The cause of colic should be determined and treated with concurrent therapy.

Pigs
2.2 mg flunixin per kg bodyweight (equivalent to2 ml of product per 45 kg BW) deep intramuscularly, repeat 1-2 times at 12 hour intervals, depending on the effect. The injection volume should be limited to a maximum of 3 ml per injection site.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Studies on the target species have shown that product is well tolerated. Overdosing is associated with gastrointensinal toxicity.
Simultaneous application of other potentially nephrotoxic products is not recommended.
Symptoms of ataxia and motor incoordination may occur.

4.11 Withdrawal period(s)

Cattle:
Meat and offal: 4 days
Milk: 24 hours

Pigs:
Meat and offal: 23 days
Horses:
Meat and offal: 10 days
Not for use in mares which milk is intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids, fenamates.
ATC vet code: QM01AG90.

5.1 Pharmacodynamic properties

The flunixin meglumine is a nonsteroidal anti-inflammatory drug which acts by inhibition of prostaglandin synthesis thus exerting, anti-inflammatory, analgesic and antipyretic. It is the active ingredient of Flunishot used for relief of symptoms of inflammation and pain associated with musculoskeletal disorders in horses; to eliminate visceral pain associated with colic in horses; the control of acute inflammation process associated with respiratory disease in cattle and in the treatment of bovine mastitis. May be used as supportive therapy of MMA (mastitis, metritis, agalactia) syndrome in sows.

5.2 Pharmacokinetic particulars

Pharmacokinetic properties of product in cattle, horses and pigs describe 2 compartmental model with rapid distribution (between 0.5 and 5.9 hours for all the above mentioned species). Elimination is also very fast and through the urine and faeces.

	Cmax (Mg / ml)	Tmax (Min)	Terminal half-life t ½ (hours)
Horses	1.0 - 5.9	30-300	1.6
Cows	0.5 - 2.8	15-120	3-8
Pigs	1.6 - 6.8	5-45	7.9

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium formaldehyde sulfoxylate
Phenol
Disodium edetate
Monoethanolamine
Propylene glycol
Hydrochloric acid (for pH adjustment)
Water for injection

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Transparent PP bottles closed with a bromobutyl rubber stopper oversealed with aluminium caps with a capacity of 50 ml, 100 ml or 250 ml packed individually in cardboard box.Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Vet-Agro Trading Sp. z o.o.
ul. Mełgiewska 18, 20-234 Lublin, Poland

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Veterinary medicinal product is subject to medical prescription.

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Flunixin 50 mg
(as equivalent 83mg of Flunixin Meglumine)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1x50ml
1x100ml
1x250ml

5. TARGET SPECIES

Cattle, horse and pig

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Cattle:
Meat and offal: 4 days
Milk: 24 hours
Pigs:
Meat and offal: 23 days
Horses:
Meat and offal: 10 days
Not for use in mares which milk is intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

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

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

Vet-Agro Trading Sp. z o.o.
ul. Mełgiewska 18, 20-234 Lublin, Poland

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:{number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Flunixin 50 mg
(as equivalent 83mg of Flunixin Meglumine)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50ml
100ml
250ml

5. TARGET SPECIES

Cattle, horse and pig

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Cattle:
Meat and offal: 4 days
Milk: 24 hours
Pigs:
Meat and offal: 23 days
Horses:
Meat and offal: 10 days
Not for use in mares which milk is intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not exceed the recommended dose and duration of treatment.

10. EXPIRY DATE

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

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

Vet-Agro Trading Sp. z o.o.
ul. Mełgiewska 18, 20-234 Lublin, Poland

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PACKAGE LEAFLET

PACKAGE LEAFLET:
Flunishot 50 mg/ml, solution for injection for cattle, horses and pigs

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

Marketing authorisation holder:
Vet-Agro Trading Sp. z o.o.
ul. Mełgiewska 18, 20-234 Lublin, Poland

Manufacturer responsible for batch release
Vet-Agro Multi-Trade Company Sp. z o.o.
Gliniana 32, 20-616 Lublin, Poland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Flunixin

3. STATEMENT OF ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:
Active substance:
Flunixin 50 mg
(as equivalent 83mg of Flunixin Meglumine)

Excipients:
Phenol 5.0 mg
Sodium Formaldehyde sulfoxylate 2.5 mg

Clear, colorless to slightly yellow solution.
Solution for injection

4. INDICATION(S)

Horses: for the alleviation of inflammation and pain associated with musculo-skeletal disorders. For the alleviation of visceral pain associated with colic in the horse.
Cattle: temperature reduction in acute inflammatory processes of the respiratory tract and as adjunctive therapy in the treatment of acute mastitis.
Pigs: adjunctive therapy in MMA syndrome in sows.

5. CONTRAINDICATIONS

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 with haemorrhagic diathesis.
Do not use in animals with known hypersensitivity to the active substance and any of excipients.
Do not use the product within 48 hours before expected parturition in cows.
Do not use in pregnant mares.
Do not use in pregnant sows.
Do not use in sows and gilts prior to mating and in breeding boars.
Do not use in case of evidence of blood dyscrasia.

Do not use in animals suffering from iliac colic or colic associated with dehydration

6. ADVERSE REACTIONS

Flunixin meglumine is a NSAID. This group of products is associated with a risk of gastrointestinal irritation and ulcers. Administration to animals with dehydration, hypovolaemia is associated with the risk of renal failure. In pigs and horses, administration of the product may cause local irritation at the injection site. Adverse reactions may occur as a consequence of the concomitant administration of other medicinal products. 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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, horse and pig.

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

For intravenous (cattle, horses) and intramuscular (pigs) injection.

Cattle
2.2mg flunixin per kg bodyweight (equivalent to 2ml of product per 45kg BW) intravenously once a day, for up to 3 consecutive days. Must determine the cause of acute inflammatory process and start appropriate therapy.

Horses
Musculoskeletal disorders:
1.1mg flunixin per kg bodyweight (equivalent to 1ml of product per 45kg BW) intravenously once a day, up to 5 consecutive days according to clinical response.
Colic:
1.1mg flunixin per kg bodyweight (equivalent to 1ml of product per 45kg BW) intravenously. Pain alleviation usually occurs within 15 minutes. The administration can be repeated once or twice if colic recurs. The cause of colic should be determined and treated with concurrent therapy.

Pigs
2.2 mg flunixin per kg bodyweight (equivalent to2 ml of product per 45 kg BW) deep intramuscularly, repeat 1-2 times at 12 hour intervals, depending on the effect. The injection volume should be limited to a maximum of 3 ml per injection site.

9. ADVICE ON CORRECT ADMINISTRATION

Do not apply to the fat tissue.

10. WITHDRAWAL PERIOD(S)

Cattle:
Meat and offal: 4 days
Milk: 24 hours
Pigs:
Meat and offal: 23 days
Horses:
Meat and offal: 10 days
Not for use in mares which milk is intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 28 days

12. SPECIAL WARNING(S)

Special warnings for each target species:
Do not exceed the recommended dose and duration of treatment.

Special precautions for use in animals:
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 foetal membranes resulting in retained placentae.
Application of the product to animals younger than six weeks old and to old animals may involve additional risk. If such use cannot be avoided animals may require reduction of the dose and additional clinical monitoring.
Intravenous administration should be performed slowly and at body temperature to prevent shock reactions. At the first signs of incompatibility the administration must be suspended and if necessary the anti-shock treatment must be started immediately. Since flunixin meglumine can reduce clinical manifestations as a function of its anti-inflammatory activity, for example resistance to causal antibiotic therapy can be masked. Ponies may be more sensitive to adverse reactions caused by NSAIDs and therefore in these animals the product should be used with caution. In horses the cause of colic must be well determined and treated with adequate concomitant therapy.
Do not administer intra-arterially. Horses during intra-arterial administration may experience reactions such as ataxia, dyspnoea, cramps, etc., which disappear after a few minutes.
Do not apply to hypovolemic animals except those that are affected by endotoxemia or septic shock.

Administration of NSAIDs, which inhibit prostaglandin synthesis, is not recommended in animals under general anesthesia and until it is completely resolved.

Do not apply to the fat tissue.

Do not use in piglets weighing less than 6 kg.

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:
The non-steroidal anti-inflammatory products may cause reactions in sensitive individuals. People with known hypersensitivity to active substance or to any of the excipients should avoid contact with the veterinary medicinal product. Hypersensitivity reactions may be serious.
This product may cause skin and eye irritation. Avoid contact with skin or eyes.
In case of accidental contact with skin or eyes, rinse immediately with plenty of water and seek medical advice.
Avoid risk of ingestion. Do not eat, drink or smoke while handling the product. In case of ingestion of the product seek medical advice.
Avoid accidental self-injection. 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, lactation:
Safety studies showed that the product may be used in pregnant and lactating cattle.
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.
Do not use in pregnant mares and sows. The safety studies in pregnant mares and sows have not been conducted.

Interaction with other medicinal products and other forms of interaction:
Do not administer other NSAIDs in the next 24 hours. Some NSAIDs may be highly bind to plasma proteins and compete with other highly bind substances, which can lead to toxic effects. Simultaneous application of other potentially nephrotoxic products is not recommended. Flunixin may reduce the effect of some antihypertensive medicinal products by inhibiting prostaglandin synthesis, such as diuretics, ACE inhibitors, angiotensin II receptor antagonists (ARAs) and beta-blockers. Moreover it can reduce the renal elimination of some medicines, increasing their toxicity as it does with aminoglycosides.

Overdose (symptoms, emergency procedures, antidotes):
Studies on the target species have shown that product is well tolerated. Overdosing is associated with gastrointestinal toxicity.
Simultaneous application of other potentially nephrotoxic products is not recommended.
Symptoms of ataxia and motor incoordination may occur.

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

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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

Package size:
1x50ml
1x100ml
1x250ml

Not all pack sizes may be marketed.