ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETIVEX 1 (9 mg/ml) solution for infusion for cattle, horses, dogs and cats [UK (NI), IE]
VETIVEX 9 mg/ml solution for infusion for cattle, horses, dogs and cats [BE, FR, NL]
AQUALEC 9 mg/ml solution for infusion for cattle, horses, dogs and cats [DE, DK, SE]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Sodium Chloride 9 mg

Sodium: 150 mmol/litre
Chloride: 150 mmol/litre

Excipient:

Qualitative composition of excipients and other constituents
Water for injections

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, dogs and cats.

3.2 Indications for use for each target species

For the treatment of dehydration in cattle, horses, dogs and cats. It may be used to correct hypovolaemia resulting from shock or gastrointestinal disease (especially where metabolic alkalosis is present, e.g. in cases of sustained vomiting or abomasal disorders in cattle). It may be administered to meet normal fluid and electrolyte requirements when fluids cannot be given orally.

3.3 Contraindications

Do not use in animals with:
- hypernatraemia
- hyperchloraemia
- hyperhydration
- oedema (hepatic, renal, or cardiac).

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Do not use unless the solution is clear, free from visible particles and the container is undamaged.

Sodium overload may occur in animals with cardiac or renal impairment. It should be noted that sodium excretion may be impaired post-surgery/trauma.
A risk of thrombosis with intravenous infusion should be considered.
Maintain aseptic precautions.
The veterinary medicinal product should be warmed to approximately 37 °C prior to the administration of large volumes, or if the administration rate is high, in order to avoid hypothermia.
Use with caution in animals with hypokalaemia.
Serum electrolyte levels, water and acid-base balance and the clinical condition of the animal should be closely monitored during the treatment in order to prevent overdose, particularly in cases of renal or metabolic changes.
This veterinary medicinal product should not be used for longer than is necessary to correct and sustain circulating volume. This solution does not contain the appropriate electrolyte balance for longer term maintenance fluid administration.
Inappropriate/excessive use may worsen or create a metabolic acidosis.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

None known.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

It is recommended to take appropriate precautions in animals receiving corticosteroids or corticotrophins to prevent high blood pressure and excessive fluid retention during administration of large volumes.
Concomitant administration of colloids requires a dose reduction.

3.9 Administration routes and dosage

Intravenous use.
The volume and rate of infusion will depend upon the clinical condition, existing deficits of the animal, maintenance needs and continuing losses.
Generally, aim to correct hypovolaemia by 50 % initially (ideally over 6 hours but faster if necessary) and reassess by clinical examination.
Deficits are generally in the range of 50 ml/kg (mild) to 150 ml/kg (severe). An infusion rate of 15 ml/kg/hour is recommended in the absence of shock (range 5-75 ml/kg/hour).
In shock, high initial infusion rates, up to 90 ml/kg/hour, are needed. High infusion rates should not be continued for longer than 1 hour unless urine output is restored. The maximum infusion rate should be decreased in the presence of cardiac, renal and pulmonary disease.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

It is recommended to maintain a serum sodium less than or equal to 130 mEq / l. In the presence of volume overload signs, treatment should involve administering diuretics and stopping the infusion.
Overdose may lead to hypernatraemia, hyperchloraemia, hypokalaemia, cardiac decompensation, hyperhydration and metabolic acidosis.
Clinical signs of excessive overdose include restlessness, hypersalivation, shivering, tachycardia, serous nasal discharge, tachypnoea, moist lung sounds, coughing, protrusion of the eye from the orbit, widespread oedema, vomiting and diarrhoea.
Long-term infusion may cause electrolyte imbalance. Saline solution is not balanced, and it may cause acidaemia because it will increase renal elimination of bicarbonate. Prolonged use may cause hypokalaemia.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: zero days.
Milk: zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QB05BB01

4.2 Pharmacodynamics

Sodium chloride and water are normal constituents of the plasma of animals.
Sodium is the major cation of the extracellular space and regulates the size of this space together with other anions.
The sodium content and the fluid homeostasis of the body are closely related. Each deviation of the plasma sodium concentration from the physiological one simultaneously affects the fluid status of the body.
An increase in the sodium content of the body also means reduction of the body's free water content independent of the serum osmolarity.
A 0.9 per cent sodium chloride solution has the same osmolarity as plasma. Administration of this solution primarily leads to a replenishment of the interstitial space which is about 2/3 of the entire extracellular space. Only 1/3 of the administered volume remains in the intravascular space.

4.3 Pharmacokinetics

Sodium chloride administered by the intravenous route quickly joins the normal distribution and metabolism of sodium chloride and water, in the intracellular and extracellular spaces.
Sodium and chloride are normal components of the body and their balance is maintained by the kidneys. The sodium level of the veterinary medicinal product is similar to the physiological level in the serum.
The kidneys are the major regulator of the sodium and water balance. In cooperation with the hormonal control mechanisms (renin-angiotensin-aldosterone system, antidiuretic hormone), the kidneys are primarily responsible for the maintenance of a constant volume of the extracellular space and regulation of its fluid composition.
Chloride is exchanged for hydrogen carbonate in the tubule system. Thus, it is involved in the regulation of the acid-base balance.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
100 ml: 18 months.
500 ml, 1000 ml and 2000 ml: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Do not store above 25 °C.
Do not freeze.

5.4 Nature and composition of immediate packaging

Polyvinylchloride infusion bag overwrapped with polypropylene.
Pack sizes: Individual fluid bags of 100 ml, 500 ml, 1000 ml and 2000 ml, each supplied with a package leaflet, or boxes containing 40 x 100 ml, 50 x 100 ml, 15 x 500 ml, 20 x 500 ml, 10 x 1000 ml, 4 x 2000 ml and 5 x 2000 ml.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater <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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

{name}

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/08/2013.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

LABEL TO BE GLUED ON OUTER CARBOARD BOX FOR MULTI-PACKS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETIVEX 1 (9 mg/ml) solution for infusion [UK (NI), IE]
VETIVEX 9 mg/ml solution for infusion [BE, FR, NL]
AQUALEC 9 mg/ml solution for infusion [DE, DK, SE]

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:

Sodium chloride 9 mg

3. PACKAGE SIZE

40 x 100 ml, 50 x 100 ml, 15 x 500 ml, 20 x 500 ml, 10 x 1000 ml, 4 x 2000 ml, 5 x 2000 ml.

4. TARGET SPECIES

Cattle, horses, dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: zero days.
Milk: zero hours.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Do not freeze.

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

{Name}

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL ON FLUID BAG/100 ml, 500 ml, 1000 ml, 2000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETIVEX 1 (9 mg/ml) solution for infusion [UK (NI), IE]
VETIVEX 9 mg/ml solution for infusion [BE, FR, NL]
AQUALEC 9 mg/ml solution for infusion [DE, DK, SE]

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Sodium chloride 9 mg

3. TARGET SPECIES

Cattle, horses, dogs and cats.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Intravenous use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: zero days.
Milk: zero hours.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

VETIVEX 1 (9 mg/ml) solution for infusion for cattle, horses, dogs and cats [UK (NI), IE]
VETIVEX 9 mg/ml solution for infusion for cattle, horses, dogs and cats [BE, FR, NL]
AQUALEC 9 mg/ml solution for infusion for cattle, horses, dogs and cats [DE, DK, SE]

2. Composition

Each ml contains:

Active substance:
Sodium chloride 9 mg
Sodium: 150 mmol/litre
Chloride: 150 mmol/litre

Clear, colourless solution.

3. Target species

Cattle, horses, dogs and cats.

4. Indications for use

For the treatment of dehydration in cattle, horses, dogs and cats.
To correct hypovolaemia resulting from shock or gastrointestinal disease (especially where metabolic alkalosis is present, e.g. in cases of sustained vomiting or abomasal disorders in cattle).
May be administered to meet normal fluid and electrolyte requirements when fluids cannot be given orally.

5. Contraindications

Do not use in animals with:
- hypernatraemia
- hyperchloraemia
- hyperhydration
- oedema (hepatic, renal, or cardiac).

6. Special warnings

Special precautions for safe use in the target species:
Do not use unless the solution is clear, free from visible particles and the container is undamaged.
Sodium overload may occur in animals with cardiac or renal impairment. It should be noted that sodium excretion may be impaired post-surgery/trauma.
A risk of thrombosis with intravenous infusion should be considered.
Maintain aseptic precautions.
The veterinary medicinal product should be warmed to approximately 37 °C prior to the administration of large volumes, or if the administration rate is high, in order to avoid hypothermia.
Use with caution in animals with hypokalaemia.

Serum electrolyte levels, water and acid-base balance and the clinical condition of the animal should be closely monitored during the treatment in order to prevent overdose, particularly in cases of renal or metabolic changes.
This veterinary medicinal product should not be used for longer than is necessary to correct and sustain circulating volume. This solution does not contain the appropriate electrolyte balance for longer term maintenance fluid administration.
Inappropriate/excessive use may worsen or create a metabolic acidosis.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
It is recommended to take appropriate precautions in animals receiving corticosteroids or corticotrophins to prevent high blood pressure and excessive fluid retention during administration of large volumes.
Concomitant administration of colloids requires a dose reduction.

Overdose:
It is recommended to maintain a serum sodium less than or equal to 130 mEq/l. In the presence of volume overload signs, treatment should involve administering diuretics and stopping the infusion.
Overdose may lead to hypernatraemia, hyperchloraemia, hypokalaemia, cardiac decompensation, hyperhydration and metabolic acidosis.
Clinical signs of excessive overdose include restlessness, hypersalivation, shivering, tachycardia, serous nasal discharge, tachypnoea, moist lung sounds, coughing, protrusion of the eye from the orbit, widespread oedema, vomiting and diarrhoea.
Long term infusion may cause electrolyte imbalance. Saline solution is not balanced, and it may cause acidaemia because it will increase renal elimination of bicarbonate. Prolonged use may cause hypokalaemia.

Major incompatibilities:
None known.

7. Adverse events

None known.

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: {national system details}.

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

Intravenous use.
The volume and rate of infusion will depend upon the clinical condition, existing deficits of the animal, maintenance needs and continuing losses.
Generally, aim to correct hypovolaemia by 50 % initially (ideally over 6 hours but faster if necessary) and reassess by clinical examination.
Deficits are generally in the range of 50 ml/kg (mild) to 150 ml/kg (severe). An infusion rate of 15 ml/kg/hour is recommended in the absence of shock (range 5-75 ml/kg/hour).

In shock, high initial infusion rates, up to 90 ml/kg/hour, are needed. High infusion rates should not be continued for longer than 1 hour unless urine output is restored. The maximum infusion rate should be decreased in the presence of cardiac, renal and pulmonary disease.

9. Advice on correct administration

Directions for use:
Remove the pack from the protective overwrap by tearing downwards from the serrated edge.
Remove the port plug protecting the sterile giving port.
Insert the administration set fully to produce a leak-proof connection and suspend the bag from an infusion stand.
An air inlet is not required.
Prime and regulate the administration set in accordance with the manufacturer's instructions. If the administration set becomes blocked, do not pump solution back into the pack, replace equipment.

10. Withdrawal periods

Meat and offal: zero days.
Milk: zero hours.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C.
Do not freeze.
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 immediate packaging: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater 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 authorisation numbers and pack sizes

Polyvinylchloride infusion bags overwrapped with polypropylene.
Pack sizes: Individual fluid bags of 100 ml, 500 ml, 1000 ml and 2000 ml, each supplied with a package leaflet, or boxes containing 40 x 100 ml, 50 x 100 ml, 15 x 500 ml, 20 x 500 ml, 10 x 1000 ml, 4 x 2000 ml and 5 x 2000 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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:

Manufacturer responsible for batch release:
SC Infomed Fluids SRL
50 Theodor Pallady Blvd
District 3
032266 Bucharest
Romania

Or

Industria Farmaceutica Galenica Senese S.R.L
Via Cassia Nord, 351
53014 Monteroni
D'arbia (SI)
Italy

The printed leaflet will include only the actual batch release site used.

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information