SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypertonic 72 mg/ml solution for infusion for cattle, cattle (calves), horses, dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Sodium chloride 72 mg

Approximate ionic content in millimoles per litre:
Sodium 1232 mmol/litre
Chloride 1232 mmol/litre

Excipients:

Qualitative composition of excipients and other constituent
Water for injections

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, cattle (calves), horses, dogs and cats.

3.2 Indications for use for each target species

As adjunctive therapy in the treatment of circulatory shock (hypovolaemic or endotoxaemic).

3.3 Contraindications

Do not use in animals with:
- Hypertonic hyperhydration (characterised by oedema);
- Renal insufficiency;
- Severe electrolyte disturbances;
- Uncontrolled haemorrhage;
- Pulmonary oedema;
- Retention of water and sodium chloride;
- Cardiac insufficiency;
- Hypertension;
- Hypertonic dehydration (characterised by thirst).

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.

Maintain aseptic precautions.

Administration of the solution must be accompanied by an opportunity for the animal to drink ad libitum.

This veterinary medicinal product should ideally 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.

Any existing haemorrhage should be stopped or controlled before treatment.

Hypertonic solutions must be administered solely by the intravenous route.

Animals treated with this veterinary medicinal product should be closely observed for possible deterioration of the clinical condition as a consequence of treatment.

Repeated infusion should only be performed after checking sodium concentration and acid-base status.

Rapid infusion of hypertonic NaCl can lead to myelinolysis in the brain in animals with chronic hyponatraemia.

Do not use the veterinary medicinal product as a vehicle for the administration of other veterinary medicinal products.

Care should be taken to avoid the use of excessive doses (>8 ml/kg) and excessive dose rates (>1 ml/kg/minute).

Excessive administration of chloride may, due to the electrolytes' interaction with the body's bicarbonate buffer system exert an acidifying effect. Therefore, in clinical instances accompanied by acidosis and hyperchloremia, special care has to be taken if this veterinary medicinal product is to be infused.
Sodium chloride administration may aggravate a pre-existing hypokalaemia.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
None.

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

3.6 Adverse events

Cattle, cattle (calves), horses, dogs and cats

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Death[a]
Undetermined frequency (cannot be estimated from the available data)	Hypokalaemia[b], Haemolysis[c], Haemoglobinuria[c] Oedema[c,d]

	Hypotension[c], Arrhythmia[c] Pulmonary oedema[c,d], Respiratory tract disorder[c,e], Hyperventilation[c] Polyuria[f] Thrombosis Injection site pain[g]

[a] Due to erroneous administration of sodium to dehydrated animals which may increase the existing extracellular hypertonia, with aggravation of existing disorders.

[b] May be induced by an excess of sodium and may be aggravated by the existence of continued loss of potassium and hyperchloraemia.

[c] After rapid administration.

[d] Especially in cases of concurrent cardiac or renal insufficiency.

[e] Bronchoconstriction.

[f] With formation of hypertonic urine.

[g] Administration into small peripheral veins may cause signs of pain.

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 of the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Administer with care to animals that have had prolonged treatment with corticosteroids having a mineralocorticoid action.

3.9 Administration routes and dosage

Intravenous use.

The infusion should ideally be warmed to approximately 37 °C prior to administration.

Recommended doses are in the range 4 -8 ml/kg, and an infusion rate of 1 ml/kg/minute should not be exceeded.

The veterinary medicinal product should be used in conjunction with conventional fluid therapy. The administration of the veterinary medicinal product is usually followed by the intravenous administration of an isotonic intravenous fluid (e.g. an intravenous 0.9% sodium chloride solution). Fluid output, plasma sodium concentration and blood pressure should be monitored.

Adequate access to drinking water should also be provided.

Strict observation of the patient is necessary to safeguard the maintenance of correct diuresis.

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

Overdose of hypertonic sodium chloride solution may lead to an increase in the extracellular volume (extracellular hyperhydration).

Hyperhydration is manifest by agitation and hypersalivation: in these cases, it is appropriate to reduce the rate of infusion drastically or to stop the infusion.

Strict observation of the patient is needed to avoid causing cardiovascular overload and pulmonary or cerebral oedema.

An increase of serum osmolarity over 350 mOsm/l may produce cerebral dysfunction and coma.

Overdose of the veterinary medicinal product can cause hypernatraemia. If hypernatraemia is present, it should be corrected slowly, using water orally if possible, or intravenous 0.9 % sodium chloride solution, or for less severe hypernatraemia, an intravenous isotonic electrolyte solution with a low sodium chloride concentration.

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

The solution is used as adjunctive therapy in the treatment of circulatory shock. It is intended to provide an interim boost to cardiovascular function, pending restoration of the circulatory volume by conventional isotonic intravenous rehydration solutions. It is intended to improve cardiac output and cause a favourable redistribution of blood flow, to the renal and visceral circulation in particular.

4.3 Pharmacokinetics

Intravenous infusion ensures rapid distribution.
The kidneys excrete excess sodium and chloride, particularly by reducing the secretion of aldosterone, resulting in the elimination of hypertonic urine. Hypertonia of the extracellular fluid stimulates osmoreceptors with increased secretion of antidiuretic hormone, which reduces the diuresis. Hypertonia of the intracellular fluid causes thirst, so the animal will drink until the normal osmotic pressure or osmolality of the body is restored.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging : use immediately.

This veterinary medicinal product does not contain an antimicrobial preservative. It is intended for single use only and unused contents should be discarded.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Polyvinyl chloride (PVC) infusion bags sealed individually in a polypropylene over-wrap with one additive addition port (PVC) and one twist-off administration port (PVC).
Individual fluid bags are supplied with a package leaflet each, or in multi packs in boxes.

Pack sizes:
Infusion bag with 500 ml solution for infusion.
Infusion bag with 3000 ml solution for infusion.
Infusion bag with 5000 ml solution for infusion.
Box with 15 x 500 ml infusion bags with solution for infusion.
Box with 20 x 500 ml infusion bags with solution for infusion.
Box with 3 x 3000 ml infusion bags with solution for infusion.
Box with 4 x 3000 ml infusion bags with solution for infusion.
Box with 2 x 5000 ml infusion bags with solution for infusion.

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

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 16/11/2017.

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

This information is printed onto the label which is stuck onto the box for multi-packs

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypertonic 72 mg/ml solution for infusion

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Sodium chloride 72 mg

3. PACKAGE SIZE

15 x 500 ml, 20 x 500 ml, 3 x 3000 ml, 4 x 3000 ml, 2 x 5000 ml.

4. TARGET SPECIES

Cattle, cattle (calves), horses, dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

i.v.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: Zero days;
Milk: Zero hours.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened 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

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

This information is printed on the label glued on the fluid bag for the individual presentation

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypertonic 72 mg/ml solution for infusion

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Sodium chloride 72 mg

3. PACKAGE SIZE

500 ml, 3000 ml, 5000 ml

4. TARGET SPECIES

Cattle, cattle (calves), horses, dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

i.v.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: Zero days;
Milk: Zero hours.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened 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

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label for FLUID BAG – 500 ml; 3000 ml and 5000 ml used in multi-pack presentation

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypertonic 72 mg/ml solution for infusion

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Sodium chloride 72 mg

3. TARGET SPECIES

Cattle, cattle (calves), horses, dogs and cats.

4. ROUTES OF ADMINISTRATION

i.v.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: Zero days;
Milk: Zero hours.

6. EXPIRY DATE

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

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET (used for multi-pack and individual pack)

1. Name of the veterinary medicinal product

Hypertonic 72 mg/ml solution for infusion for cattle, cattle (calves), horses, dogs and cats

2. Composition

Each ml contains:
Active substance:
Sodium chloride 72 mg

Approximate ionic content in millimoles per litre:
Sodium 1232 mmol/litre
Chloride 1232 mmol/litre

Clear, colourless solution.

3. Target species

Cattle, cattle (calves), horses, dogs and cats.

4. Indications for use

As adjunctive therapy in the treatment of circulatory shock (hypovolaemic or endotoxaemic).

5. Contraindications

Do not use in animals with:
- Hypertonic hyperhydration (characterised by oedema);
- Renal insufficiency;
- Severe electrolyte disturbances;
- Uncontrolled haemorrhage;
- Pulmonary oedema;
- Retention of water and sodium chloride;
- Cardiac insufficiency;
- Hypertension;
- Hypertonic dehydration (characterised by thirst).

6. Special warnings

Special warnings:
None.

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.
Maintain aseptic precautions.

Administration of the solution must be accompanied by the opportunity for the animals to drink ad libitum.

This veterinary medicinal product should ideally 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.

Any existing haemorrhage should be stopped or controlled before treatment.

Hypertonic solutions must be administered solely by the intravenous route.

Animals treated with this veterinary medicinal product should be closely observed for possible deterioration of the clinical condition as a consequence of treatment.

Repeated infusion should only be performed after checking sodium concentration and acid-base status.

Rapid infusion of hypertonic NaCl can lead to myelinolysis in the brain in animals with chronic hyponatraemia.

Do not use this veterinary medicinal product as a vehicle for the administration of other veterinary medicinal products.

Care should be taken to avoid the use of excessive doses (>8 ml/kg) and excessive dose rates (>1 ml/kg/minute).

Excessive administration of chloride may, due to the electrolytes' interaction with the body's bicarbonate buffer system exert an acidifying effect. Therefore, in clinical instances accompanied by acidosis and hyperchloremia, special care has to be taken if this veterinary medicinal product is to be infused.
Sodium chloride administration may aggravate a pre-existing hypokalaemia.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
None.

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 of the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Administer with care to animals that have had prolonged treatment with corticosteroids having a mineralocorticoid action.

Overdose:
Overdose of hypertonic sodium chloride solution may lead to an increase in the extracellular volume (extracellular hyperhydration).

Hyperhydration is manifest by agitation and hypersalivation; in these cases, it is appropriate to reduce the rate of infusion drastically or to stop the infusion.

Strict observation of the patient is needed to avoid causing cardiovascular overload and pulmonary or cerebral oedema.

An increase of serum osmolarity over 350 mOsm/l may produce cerebral dysfunction and coma.

Overdose of the veterinary medicinal product can cause hypernatraemia. If hypernatraemia is present, it should be corrected slowly, using water orally if possible, or intravenous 0.9 % sodium chloride solution, or for less severe hypernatraemia, an intravenous isotonic electrolyte solution with a low sodium chloride concentration.

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, cattle (calves), horses, dogs and cats

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Death[a]
Undetermined frequency (cannot be estimated from the available data)	Hypokalaemia[b], Haemolysis[c], Haemoglobinuria[c] Oedema[c, d] Hypotension[c], Arrhythmia[c] Pulmonary oedema[c, d],Respiratory tract disorder[c,e], Hyperventilation[c] Polyuria[f] Thrombosis Injection site pain[g]

[a] Due to erroneous administration of sodium to dehydrated animals which may increase the existing extracellular hypertonia, with aggravation of existing disorders.

[b] May be induced by an excess of sodium and may be aggravated by the existence of continued loss of potassium and hyperchloraemia.

[c] After rapid administration.

[d] Especially in cases of concurrent cardiac or renal insufficiency.

[e] Bronchoconstriction.

[f] With formation of hypertonic urine.

[g] Administration into small peripheral veins may cause signs of pain.

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 infusion should ideally be warmed to approximately 37 °C prior to administration.

Recommended doses are in the range 4 -8 ml/kg, and an infusion rate of 1 ml/kg/minute should not be exceeded.

The veterinary medicinal product should be used in conjunction with conventional fluid therapy. The administration of the veterinary medicinal product is usually followed by the intravenous administration of an isotonic intravenous fluid (e.g. an intravenous 0.9 % sodium chloride solution). Fluid output, plasma sodium concentration and blood pressure should be monitored.

Adequate access to drinking water should also be provided.

Strict observation of the patient is necessary to safeguard the maintenance of correct diuresis.

9. Advice on correct administration

Warm the pack to approximately 37 °C.
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 bag and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging : use immediately.

This veterinary medicinal product does not contain an antimicrobial preservative. It is intended for single use only and unused contents should be discarded.

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

Polyvinyl chloride (PVC) infusion bags sealed individually in a polypropylene over-wrap with one additive addition port (PVC) and one twist-off administration port

(PVC). Individual fluid bags are supplied with a package leaflet each, or in multi packs in boxes.

Pack sizes: Individual infusion bag with 500 ml, 3000 ml or 5000 ml solution for infusion, or boxes containing 15 x 500 ml, 20 x 500 ml, 3 x 3000 ml, 4 x 3000 ml or 2 x 5000 ml infusion bags with solution for infusion.

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:
Dechra Regulatory B.V.

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[1]

[1] 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