

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETIVEX 6 (Glucose 5 % w/v Intravenous Infusion BP (Vet))

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Glucose monohydrate 5.5 % w/v
(equivalent to anhydrous glucose 5.0 % w/v)

Each one litre provides approximately 200 kcal.

3. PHARMACEUTICAL FORM

A clear, colourless solution for infusion.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, calves, horses, dogs and cats.

4.2 Indications for use, specifying the target species

This product is administered by intravenous infusion for the treatment of dehydration (in the absence of shock) in cattle, calves, horses, dogs and cats. It is used to replace water when it cannot be taken or retained orally.

Glucose infusions are used to correct hypernatraemia (by replacing lost water) and hyperkalaemia (through the promotion of insulin production which in turn causes potassium to move from plasma into cells). It is not a significant calorie source but can provide transient improvement of hypoglycaemia.

4.3 Contraindications

This product should not be administered to hyperglycaemic animals.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

- i. Special precautions for use in animals

This product should be used with care in diabetic patients.

A risk of thrombosis with intravenous infusion should be considered.

This product should not be administered at rate in excess of 10 ml/kg/hour, otherwise glycosuria and osmotic diuresis may result. Furthermore, severe or long-standing hypernatraemia should be corrected gradually.

- ii. Special precautions to be taken by the person administering the medicinal product to animals

No special precautions required.

- iii. Other precautions

None required.

4.6 Adverse reactions (frequency and seriousness)

Monitor fluid output and blood glucose.

4.7 Use during pregnancy and lactation or lay

Use under veterinary supervision.

4.8 Interaction with other medicaments and other forms of interaction

Incompatibility with certain antibiotics and heparin are recognised.

4.9 Amounts to be administered and administration route

This product should be administered intravenously at a rate not exceeding 10 ml/kg/hour.

Maintain aseptic precautions

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

Monitor fluid output and blood glucose.

4.11 Withdrawal periods

Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Blood substitutes and perfusion solutions, I.V. solutions, Solutions for parenteral nutrition

ATC Vet Code: QB05BA03. Solutions affecting the electrolyte balance

5.1 Pharmacodynamic properties

Glucose 5 % w/v Intravenous Infusion BP (Vet) is used as a replacement source of water and glucose for animals who cannot be given rehydration fluids orally. It is temporarily isotonic (thereby avoiding causing osmotic shock to red blood cells), the glucose is then metabolised leaving water. The glucose can provide a transient source of nutrient and will aid in correction of a hyperkalaemia.

5.2 Pharmacokinetic properties

Intravenous infusion ensures rapid distribution. The constituents of the infusion solution will be metabolised and excreted through the same pathways as those substances derived from normal dietary sources.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

None stated.

6.3 Shelf-life

Do not use unless the solution is clear, free from visible particles, and the container is undamaged.

Unopened: 2 years.

After opening: The product does not contain an antimicrobial preservative. It is intended for single use only and any unused contents should be discarded.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Presented in polyvinylchloride (PVC) infusion bags, over-wrapped with polypropylene, in cartons of 20 x 500 ml and 10 x 1000 ml.

Not all pack sizes may be marketed.

Each carton contains sufficient number of package leaflets so that individual units may be supplied.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Dechra Limited
Dechra House
Jamage Industrial Estate
Talke Pits
Stoke-On-Trent
Staffordshire
ST7 1XW

8. MARKETING AUTHORISATION NUMBER

Vm 10434/4057

9. DATE OF RENEWAL OF THE AUTHORISATION

22 April 2008

10. DATE OF REVISION OF THE TEXT

March 2011