

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Glucose 40% w/v Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Qualitative composition

Glucose (anhydrous)

Quantitative composition

40.00 % w/v

Excipients

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

A clear, sterile, aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and sheep.

4.2 Indications for use, specifying the target species

For the treatment of primary and secondary hypoglycaemia, acetonæmia and as a source of energy in cattle.

As an aid in the treatment of pregnancy toxæmia in sheep.

4.3 Contraindications

Do not give by subcutaneous injection.

4.4 Special warnings for each target species

Intravenous injection should be given slowly, preferably not exceeding 0.5 ml/kg/hour.

Do not administer by the subcutaneous route.

When acidosis is severe, and renal failure present, treatment is unlikely to be efficacious.

4.5 Special precautions for use

i. Special precautions for use in animals

This product does not contain an antimicrobial preservative. Any solution

remaining in the vial following withdrawal of the required dose should be discarded.

- ii. Special precautions for the person administering the veterinary medicinal product to animals

Care should be taken to avoid accidental self-injection.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Rapid intravenous injection of dextrose will cause the renal threshold for glucose to be exceeded, with consequent clinical signs of stress and loss of glucose in the urine. For best results intravenous infusions should be given slowly, preferably at a rate not exceeding 0.5 ml/kg/hour.

4.7 Use during pregnancy, lactation or lay

Not contraindicated.

4.8 Interaction with other medicinal products and other forms of interaction

None known (supplementary treatment can be provided as appropriate).

4.9 Amount(s) to be administered and administration route

Cattle: 1 ml/kg, by slow intravenous injection. In some cases, a higher dose rate may be required but should only be given on veterinary advice.
Treatment may be repeated as necessary.

Sheep: 1 ml/kg to be given by slow intravenous injection. Treatment may be repeated after 6 hours if necessary.

The solution should be warmed to body temperature before use.
Strict aseptic precautions should be observed in preparation of the site of injection.
Do not exceed the recommended dosage.

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

See 4.6 regarding renal crisis; no treatment specified.

4.11 Withdrawal periods

Cattle and sheep:
Meat: zero days
Milk: zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

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

ATC Vet Code:

QB05BA03

5.1 Pharmacodynamic properties

Glucose is often a constituent of oral and parenteral fluid therapies including those for parenteral nutrition. Solutions of glucose are widely used in the treatment of metabolic diseases in which hypoglycaemia is an important component. Examples of these conditions include, pregnancy toxaemia or twin-lamb disease in sheep, acetonæmia or ketosis in cattle.

Acetonæmia in cattle is also known as ketosis. In sheep, acetonæmia is usually known as pregnancy toxaemia or twin lamb disease. Treatment of acetonæmia is usually very successful in cattle but in sheep the mortality rates, even after treatment, often exceed 50 %.

5.2 Pharmacokinetic properties

Glucose is of critical importance to normal physiology and cellular metabolism. Blood glucose concentrations in healthy animals are closely controlled and in hyperglycaemia the excess blood glucose is normally removed from the circulation. The removal occurs by several routes including renal clearance. The renal threshold of blood glucose is readily exceeded. Intravenous supplementation can only be achieved by use of hypertonic solutions, for example glucose 40 % w/v solution. This glucose solution can make a useful contribution to the energy requirements of the body. However, it is easy to exceed the renal threshold and induce a diuresis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 1 year.

6.4 Special precautions for storage

Do not store above 25°C.

Protect from light.

This product does not contain an antimicrobial preservative. Any remaining solution in the bottle following withdrawal of the required dose should be discarded.

6.5 Nature and composition of immediate packaging

400 ml type II amber glass bottle, fitted with a grey rubber stopper and push off polypropylene cap.

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 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

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 36408/4013

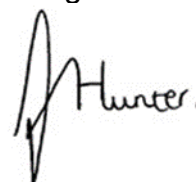
9. DATE OF FIRST AUTHORISATION

20 April 1994

10. DATE OF REVISION OF THE TEXT

August 2021

Approved 18 August 2021

A handwritten signature in black ink, appearing to read 'J. Hunter.', is positioned below the approval date.