Issued: 8 June 2010
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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Insuvet Neutral 100 IU/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	per 1 ml
Insulin, Bovine	100 IU
E*xcipients*	
Phenol	0.65 mg
Cresol, crude	1.60 mg

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
White to nearly white solution

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

For the treatment of insulin-dependent diabetes mellitus in the dog or cat, when those animals are presented in a ketoacidotic state.

4.3 Contraindications

Insulin is contra-indicated in hypoglycaemia.

4.4 Special warnings for each target species

It is essential to implement careful dose monitoring when treating keto-acidotic animals, in particular blood glucose levels

4.5 Special precautions for use
Special precautions for use in animals

It is recommended that appropriately-graduated syringes are used and a new syringe used for each injection.
Insuvet Neutral should not be administered subcutaneously to dehydrated animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Care should be taken to avoid accidental self-injection. In the event of accidental self-injection, medical advice MUST be sought immediately, showing the doctor this label.
Persons who are hypersensitive (allergic) to insulin or other ingredients in this product should wear impermeable rubber gloves, when handling the product.
Avoid contact with skin and eyes.
In the event of accidental eye or skin contact, wash/irrigate the area with clean running water.
Seek medical attention if irritation persists.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Not known.

4.7 Use during pregnancy, lactation or lay

The insulin requirements will change during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

It is well recognised that corticosteroids and progestagens are strongly antagonistic to the effects of insulin. For successful control of diabetes in an individual, consideration needs to be give to the potential effects of either exogenous or endogenous sources of these hormones and, where appropriate, removing the source of the hormone.

4.9 Amounts to be administered and administration route

Mix the product gently before use by inverting the vial.

For intravenous, intramuscular or subcutaneous administration.

Injections should be made immediately upon withdrawal from the vial.

In treatment of animals in the ketoacidotic state it is vital that fluid and metabolic imbalances should be corrected by appropriate therapy as part of the stabilisation process.

If treatment of hyperglycaemia is commenced, the product may be given by continuous low dose intravenous infusion at a dosage of 5 IU/100 ml of electrolyte, administered at the rate of 50-100 ml/hour for dogs and 50 ml/hour for cats.

Initial stabilisation:

An initial loading dose of 0.25 IU/kg of Insuvet Neutral by IM route should be administered to the patient. This should be followed by administration of 0.1 IU/kg by IM route hourly, with hourly monitoring of blood glucose level. When the blood glucose level has decreased to <15 mmol/L (usually within a 4 – 8 hour period), 5% dextrose should be added to the fluids. When normal hydration has been restored and the blood glucose level is 8-14 mmol/L, then 0.5 IU/kg of Insuvet Neutral should be administered subcutaneously every 6 hours. Once the patient is eating and drinking voluntarily and the ketoacidosisis corrected, therapy with Lente or PZI may be commenced at the discretion of the veterinary surgeon.

An intravenous infusion rate of 0.1 IU/kg/hr has also been advocated for the initial treatment of ketoacidosis. Because insulin has been shown to bind to glass and plastic, the first 50 ml of the infusion should be discarded.

NOTE: these recommendations are intended for guidance purposes only. The veterinary surgeon's assessment of the clinical response to therapy will determine dosage and frequency of administration.

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

Overdosage causes hypoglycaemia, which may be recognised initially by signs of drowsiness, weakness and unsteady movements which, if untreated, will lead to collapse, convulsions, coma and death. In cases of overdosage your veterinary surgeon should be consulted at the earliest opportunity and immediate intravenous dextrose administration considered. If the animal is at home and particularly if convulsing, sugar water or syrup may be carefully introduced into the animal's mouth until the convulsions stop and veterinary attention can be provided.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QA10AB02
Insulins and analogues for injection, fast acting.

5.1 Pharmacodynamic properties

Insuvet Neutral contains a regular soluble insulin of bovine origin. Soluble insulin has a quick onset and short duration of action suitable for use in diabetes mellitus emergency.

5.2 Pharmacokinetic particulars

Insuvet Neutral has a rapid onset and short duration of activity when used intravenously, intramuscularly or subcutaneously and is normally used to treat dogs or cats presented in a ketoacidotic state. It is essential in such cases to correct the fluid and metabolic imbalance as soon as possible.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Cresol, crude
Glycerol
Sodium phosphate dodecahydrate
Hydrochloric acid (for pH adjustment)
Phosphoric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)
Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

Store in a refrigerator (+2°C to +8°C).
Do not freeze.
Keep the container in the outer carton.

6.5 Nature and composition of immediate packaging

10 ml clear, neutral glass type I vials closed with a chlorobutyl rubber bung with an aluminium overseal.

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

Pfizer Ltd.
Ramsgate Road
Sandwich
Kent
CT13 9NJ

Pfizer Healthcare Ireland
Trading as: Pfizer Animal Health
Ringaskiddy
Co. Cork
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 00057/4275

VPA 10019/121/1

9. DATE OF THE FIRST AUTHORISATION

4th August 1993

7th October 2005

10. DATE OF REVISION OF THE TEXT

29th October 2009