Issued: 8 June 2010
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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Insuvet Lente 100 IU/ml Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	per 1 ml
Insulin, Bovine	100 IU

Excipients

Methyl parahydroxybenzoate	1.0 mg

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
White to nearly white suspension

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 and cat, where a medium to extended duration of action is required.

4.3 Contraindications

Insulin is contra-indicated in hypoglycaemia.

4.4 Special warnings for each target species

When adjusting doses it is recommended that the maximum change made, either increase or decrease, is 2 IU daily. The full effects of a dose change may not be seen until up to 3 days afterwards. Blood glucose should be monitored when changing doses and this potential 3 day delay should be considered before making further changes. The requirements for insulin will vary with changes in diet and exercise, during illness, stress, oestrus, pregnancy, liver and kidney diseases and when other medication with hypo- or hyperglycaemic activity is given.

4.5 Special precautions for use

Special precautions for use in animals

For subcutaneous administration only.
It is recommended that appropriately graduated syringes are used and a new syringe used for each injection.

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 both endogenous corticosteroids and progestagens are strongly antagonistic to the effects of insulin. For successful control of diabetes in an individual, consideration needs to be given 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 administration by subcutaneous injection once or twice daily, depending on the individual response.

Injections should be made immediately upon withdrawal from the vial.

Where the animal is hyperglycaemic and non-ketoacidotic, stabilisation should be commenced with a loading dose of 0.5 IU/kg. Blood glucose must be monitored closely, and the maintenance dose adjusted accordingly. An isocaloric diet should be established.

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: QA10AC02
Insulins and analogues for Injection, intermediate – acting.

5.1 Pharmacodynamic properties

Insuvet Lente is a suspension of highly purified bovine insulin with zinc oxide, consisting of 70% insulin zinc (crystalline) and 30% insulin zinc (amorphous).

5.2 Pharmacokinetic particulars

Insuvet Lente is an intermediate acting insulin and has a medium to extended duration of action and is used subcutaneously. The onset of action is normally 1-3 hours post administration with a maximum effect at 6-12 hours and a maximum duration of 18 - 28 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methylparahydroxybenzoate
Zinc oxide
Sodium acetate trihydrate
Sodium chloride
Sodium hydroxide (for pH adjustment)
Hydrochloric acid, concentrated (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: 3 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 00057/4279

VPA 10019/120/1

9. DATE OF THE FIRST AUTHORISATION

31st July 1993

7th October 2005

10. DATE OF REVISION OF THE TEXT

29th October 2009