Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Insuvet Protamine Zinc 100 IU/ml Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	per 1 ml
Insulin, Bovine	100 IU
Excipients	
Phenol	2.50 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

Dog and cats.

4.2 Indications for use, specifying the target species

For the treatment of insulin-dependent diabetes mellitus in the dog or 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 the product 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. The vial must not be used if the contents fail to redisperse.

For administration by subcutaneous injection once or twice daily depending on the individual response.

Injections should be made immediately upon withdrawal from the vial.

A commencing dose of 0.5 IU/kg bodyweight is recommended. Monitor blood glucose closely to establish efficacy and optimal dosage.

An isocaloric daily ration should be established. A portion of the daily ration is fed before dosing. This applies whether the animal is dosed once or twice per day. The remaining portions should be offered at the estimated hypoglycaemic peak. Once the pattern of hypo- and hyperglycaemic is established, the dosage regimen should be adjusted, the maximum recommended daily change being $\pm$ 2 IU.

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 or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QA10AC02
Insulins and analogues for injection, intermediate acting.

5.1 Pharmacodynamic properties

Insuvet Protamine Zinc has a medium to extended duration of action and is used subcutaneously. The onset of action is normally 2-5 hours post administration with a maximum effect at 12-24 hours and a maximum duration of 24-36 hours. There is wide individual variability in response to insulin and these time scales are for guidance only.

5.2 Pharmacokinetic properties

Insuvet Protamine Zinc is a suspension of highly purified bovine insulin with a medium to extended duration of action.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Protamine sulphate
Sodium phosphate dodecahydrate
Zinc chloride
Glycerol
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Phosphoric acid (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 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 products or waste materials

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/122/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6th October 2010

10 DATE OF REVISION OF THE TEXT