

4.5 Special Precautions for Use

Special Precautions for use in Animals

Mix the product gently before use by inverting the vial.

Special Precautions to be Taken by the Person Administering the Veterinary Medicinal Product to Animals

In the event of accidental self-injection, medical advice must be sought immediately showing the Doctor this label and any other product literature.

In the event of accidental eye contact wash eyes immediately with plenty of cold water. If irritation persists seek medical advice.

People with known sensitivity to insulin should wear gloves.

4.6 Adverse reactions (Frequency and seriousness)

None known

4.7 Use During Pregnancy, Lactation or Lay

The insulin requirements will change during pregnancy and lactation.

4.8 Interaction with Other Medicaments and Other Forms of Interaction

None known.

4.9 Amounts to be Administered and Administration Route

For administration by subcutaneous injection.

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 0.5iu/kg bodyweight.

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 you may recognise initially by signs of drowsiness, weakness and unsteady movements which, if untreated, will lead to collapse, convulsions, coma and death. In case of overdosage you veterinary surgeon should be consulted at the earliest opportunity. 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 Periods

Not applicable.

5. PHARMACOLOGICAL PARTICULARS

This product 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 19-28 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Zinc oxide, sodium acetate, sodium chloride, water for injections.

6.2 Incompatibilities

Not known.

6.3 Shelf Life

3 years.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

6.4 Special Precautions for Storage

Store in a refrigerator (2°C-8°C).

Do not freeze.

Keep container in the outer carton to protect from light.

6.5 Nature and Contents of Immediate Packaging

10 ml Type I glass vial sealed with Type I grey bromobutyl rubber bung secured with an aluminium overseal with a plastic flip top material.

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Company:	Dechra Ltd		

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 waste material should be disposed of in accordance with national requirements.

7.0 MARKETING AUTHORISATION HOLDER

Dechra Ltd.
Dechra House
Jamage Industrial Estate
Talke Pits
Stoke-on-Trent
ST7 1XW

Legal Category: **POM-V**

8.0 MARKETING AUTHORISATION NUMBER(S)

UK: Vm 10434/4002

9.0 DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

10.0 DATE OF ANY REVISION OF THE TEXT

12/01/2006

Attachments for Section 1B

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VIAL TEXT

PETSULIN LENTE

INSULIN ZINC SUSPENSION (MIXED) BP

10 ml vial
100 iu/ml

Each ml contains: Highly purified beef insulin 100iu. Methyl-parahydroxybenzoate 0.1% as a preservative.

The vial should be shaken gently by inversion several times before the dose is withdrawn.

Read package insert before use.

Following withdrawal of the first dose use the product within 28 days. Discard unused material.

Store at 2° C -8°C. **DO NOT FREEZE.**

Keep container in the outer carton.

For animal treatment only. Keep out of the reach of children.

Once broached, use by:

POM-V

Vm 10434/4002

Dechra Veterinary Products, Cartmel Drive, Harlescott, Shrewsbury, Shropshire, SY1 3TB

CARTON TEXT

PETSULIN LENTE

INSULIN ZINC SUSPENSION (MIXED) BP

10 ml vial
100 iu/ml

Each ml contains: Highly purified beef insulin 100 iu. Methyl-parahydroxybenzoate 0.1% as a preservative.

The vial should be shaken gently by inversion several times before the dose is withdrawn.

For subcutaneous injection only.

Dosage as directed by the veterinary surgeon. Please read the enclosed leaflet carefully before use.

Store at 2°C -8°C. **DO NOT FREEZE.**

Keep container in the outer carton.

Following withdrawal of the first dose use the product within 28 days. Discard unused material.

For animal treatment only. Keep out of the reach of children.

Once broached, use by:

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DATA SHEET

PETSULIN LENTE

INSULIN ZINC SUSPENSION (MIXED) BP

Description:

Each vial of PETSULIN LENTE contains 10 ml of injectable suspension containing 100 iu insulin and 1.00 mg methyl-parahydroxybenzoate as preservative per ml.

Dosage:

Your veterinary surgeon will advise you on the dosage which you must not change except under his/her guidance. The maximum recommended change to the daily dose, either increase or decrease, is 2 iu. Your veterinary surgeon will also advise you on diet, exercise and the monitoring of your pet's condition.

Administration of dose:

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

The vial of insulin should be removed from the refrigerator and inverted several times to mix the contents gently but thoroughly. Do not shake the vial. The rubber top should be cleansed with surgical spirit before inserting the syringe needle. Remove the wrapping from a new syringe, remove the protective cover from the needle and withdraw the plunger to the appropriate mark.

Insert the needle into the vial and depress the plunger, then turn the vial upside-down and withdraw the plunger, measuring the insulin into the syringe. Then withdraw the needle from the vial. Check no air bubbles are present in the syringe, then, at the chosen site on your pet, pull up the skin and insert the needle through one side. Withdraw the plunger slightly to check the needle is not lodged in a blood vessel (remove and redirect the needle if it is), and depress the plunger. Withdraw the needle, replace the protective cover and discard the syringe. After injection gently massage the injection site to disperse the insulin.

Precautions:

The vial must not be used if the contents do not re-disperse. Injections should be made immediately upon withdrawal from the vial. Insulin requirements may vary with illness, stress, pregnancy, increased activity, other drugs or changes in diet. It is important when any of these change for your pet that you contact your veterinary surgeon. Administer only by subcutaneous injection.

In the event of accidental eye contact, wash eyes immediately with plenty of cold water. If irritation persists, seek medical advice. People with known sensitivity to insulin should wear gloves.

Storing PETSULIN LENTE:

Vials should be stored in the refrigerator between 2°C and 8°C. **On no account should they be allowed to freeze.** The contents of one vial should be used within 4 weeks of opening.

Keep container in the outer carton to protect from light.

Dispose of used packaging in the household refuse. Unused product should be returned to the Veterinary Surgeon.

Syringes:

Only syringes supplied by your veterinary surgeon for use specifically with insulin should be used. Under no circumstances must any other syringe be used. It is recommended that disposable syringes are used and a new syringe and needle are used for each injection. Additional syringes may be obtained from your veterinary surgeon or, in the case of an emergency, a pharmacist given proof of identity may supply. Ask the pharmacist for a 1/2 millilitre, 100 units/ml syringe.

What to do in case of accidental overdose

Overdosage causes hypoglycaemia, which you may recognise initially by signs of drowsiness, weakness and unsteady movements which, if untreated may lead to collapse, convulsions, coma and death. In case of overdosage you veterinary surgeon should be consulted at the earliest opportunity. If the animal is at home and convulsing, sugared water or syrup should be carefully introduced into the animal's mouth until the convulsions have stopped and veterinary attention can be provided.

What to do in case of accidental self-injection

In the event of accidental self-injection, medical advice **MUST** be sought immediately, showing the doctor this label and any other product literature.

For animal treatment only.

Keep out of the reach of children.

POM-V

Vm 10434/4002

Marketing Authorisation Holder: Dechra Ltd.

Distributed by:

Dechra Veterinary Products, Cartmel Drive, Harlescott, Shrewsbury, Shropshire, SY1 3TB

PETSULIN LENTE

Notice for veterinary surgeons

Description:

PETSULIN LENTE is a white, neutral injectable suspension of highly purified bovine insulin with zinc oxide, consisting of 70% insulin zinc (crystalline) and 30% insulin zinc (amorphous). Each 1 ml contains 100 iu insulin and 1 mg methyl-parahydroxybenzoate as preservative.

Use:

PETSULIN LENTE has a medium to extended duration of action and is administered 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. The veterinary surgeon should be aware that the onset, peak and duration of activity has been reported as being variable between dogs and, in cats, can be half that achieved in dogs.

Dosage and Administration:

Where the cat or dog is presented in a non-ketoacidotic hyperglycaemic state, stabilisation can be undertaken immediately. Depending on the degree of hyperglycaemia this may be accomplished by initiating therapy with PETSULIN Lente or PETSULIN Protamine Zinc, using a commencing dose of 0.5 iu/kg administered subcutaneously. Blood glucose must be monitored closely to establish the effect of the insulin dose. An isocaloric daily ration to maintain a healthy weight should be established. A portion of the daily ration (normally between 1/3 and 1/2 for cats and between 1/4 and 1/3 for dogs) is fed just before dosing. This applies whether the animal is dosed once daily, or twice daily. The remaining portion should be offered at the estimated maximum hypoglycaemic state. Once glucose levels have been established the insulin dose and feeding regime may be adjusted accordingly. Whenever the type of insulin, dose or feeding regime is altered, close monitoring of blood glucose should be undertaken.

Once stabilised, the animals may go home but it should be borne in mind that the insulin dose may need adjustment at this time and close monitoring initially is recommended.

When adjusting doses of insulin it is recommended that the maximum change made, either increase or decrease, is 2 iu daily. It is important to realise that the full effects of an initial dose or dose change may not be seen until up to 3 days afterwards. Blood glucose should be monitored when changing doses and this possible 3 days delay should be considered before making further changes.

Contra-indications, warnings, precautions:

Insulin is contra-indicated in hypoglycaemia.

PETSULIN LENTE must be given only by subcutaneous injection. Injections should be made immediately upon withdrawal from the vial.

The requirement for insulin will vary with changes in diet and exercise, during illness, stress, pregnancy, liver or kidney diseases and when other medication with hypo or hyperglycaemic activity is given.

Excess administration of insulin may result in insulin-induced hyperglycaemia (the Somogyi overswing). Insulin antagonism may develop. Recognised causes in the dog include exogenous glucocorticoid administration, hyperadrenocorticism, oestrus, pregnancy and chronic infection.

Overdosage causes hypoglycaemia and immediate intravenous dextrose administration should be considered. If the animal is at home and convulsing, sugared water or syrup should be carefully introduced into the animal's mouth until the convulsions stop.

Administer only by subcutaneous injection.

In the event of accidental self-injection, medical advice **MUST** be sought immediately, showing the doctor this label and any other product literature.

In the event of accidental eye contact, wash eyes immediately with plenty of cold water. If irritation persists, seek medical advice. People with known sensitivity to insulin should wear gloves.

Pharmaceutical precautions:

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

Store in a refrigerator (2°C-8°C). **DO NOT FREEZE**. The vial should be shaken gently by inversion several times before the dose is withdrawn. The vial must not be used if the contents do not re-disperse. Injections should be made immediately upon withdrawal from the vial. Following withdrawal of the first dose, use product within 28 days. Discard unused material.

Keep container in the outer carton to protect from light

Dispose of any unused product and waste material in accordance with guidance from your local waste regulation authority.

Further Information:

It is recommended that sterile disposable syringes are used for administration and a new syringe and needle used for each injection. If excessive levels of insulin are administered, blood glucose will fall rapidly. Physiological responses bring about a compensatory increase (Somogyi overswing). Veterinary surgeons should consider this when animals apparently require excessive doses of insulin.

For animal treatment only.

Keep out of the reach of children.

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Dechra Ltd.

Distributed By:
Dechra Veterinary Products, Cartmel Drive, Harlescott, Shrewsbury, Shropshire,
SY1 3TB

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