Vetsulin® CurveKit

Glucose Curve Workpad • How-to Instructions Interpretation Guidelines • Pet Diabetes Tracker



HOW TO CHART YOUR PATIENTS' GLUCOSE CURVES.

Once the patient has been on Vetsulin* (porcine insulin zinc suspension) for 5 to 7 days for dogs or 7 to 14 days for cats, admit the patient either:

- 1. First thing in the morning before eating and receiving Vetsulin®.
- 2. Right after the patient eats and receives Vetsulin® at home.

After admitting the patient, it's important that the patient follows the same routine as it does at home. Provide the same food and exercise on the same schedule it is accustomed to. Be sure to obtain a history from the owner with regard to their observations of the patient's signs of diabetes at drop-off. A current body weight should be obtained and recorded.

BLOOD SAMPLING:

Measure blood glucose every 2 hours. Ideally, continue for 12 hours if insulin is administered twice daily (BID) or for 24 hours for canine once-daily (SID) insulin administration. If the blood glucose level is <150 mg/dL, consider checking hourly measurements.

CHART:

Plot the blood glucose concentrations against time to create the blood glucose curve.

Ideal nadir or lowest blood glucose level after insulin administration:





Once you have established the nadir, then determine the duration of activity. This is the time between insulin injection and when blood glucose becomes >200-250 mg/dL for dogs or >250 mg/dL for cats after the nadir.

For dogs starting with 1x/day dosing: If blood glucose is



insulin injections may be required

At the end of the testing period, compare the glucose curve to the interpretation charts on the next page to establish a treatment plan.

NOTE:

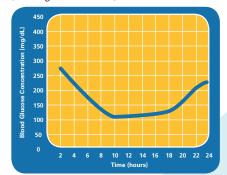
A 24-hour curve may be the only way to accurately diagnose Somogyi overswing. Sampling can be done at the marginal vein of the ear or, for dogs, on the mouth mucosa (just flip up the lip) to minimize stress.

INTERPRETING SERIAL GLUCOSE CURVES.

Serial glucose curves are a useful tool in the initial stabilization and monitoring of the diabetic dog and cat, giving the most accurate assessment on which to base changes in insulin therapy. They are vital in investigating the unstable diabetic.

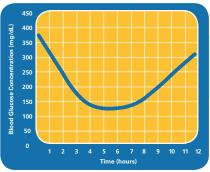
These charts show the curves you would expect to find in the stable diabetic dog and cat as well as the 4 main problem scenarios. The charts for the 4 problem scenarios are plotted against a 24-hour timeline but can be easily adapted to a 12-hour BID dosing timeline.

Ideal Blood Glucose Curve: SID Dosing in the Dog (Insulin given at time=0)



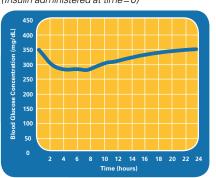
- ► The renal threshold in the dog is 180-220 mg/dL.
- A stable diabetic dog maintains a blood glucose range of 100-250 mg/dL for most of a 24-hour period.

Ideal Blood Glucose Curve: 12-hour BID Dosing in the Cat (Insulin given at time=0)



- Ideally, the cat's blood glucose levels should be between 120-300 mg/dL for the majority of the day.
- The renal threshold in the cat is 200-280 mg/dL

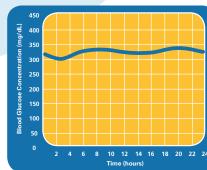
Insufficient Insulin Dose (Insulin administered at time=0)



Action: In general, increase insulin dose in dogs. Note that insufficient insulin dose can be difficult to determine in diabetic cats due to stress-induced hyperglycemia, but if the cat's clinical signs have not resolved, the nadir is >200 mg/dL and Somogyi overswing has been ruled out, increase the dose in 0.5-1.0 IU increments.

Insulin Resistance

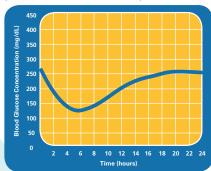
(Insulin administered at time=0)



Action: Investigate cause, eg, Cushing's disease hyperprogesteronism, antibody production, owner issues, injection issues, or use of the wrong type of syringe (see Diagnostic Tests to Consider for the Evaluation of Insulin Resistance in Diabetic Dogs and Cats). Consideration should be given to Somogyi overswing, which can present as persistent hyperglycemia for a few days following the

Rapid Metabolism of Insulin

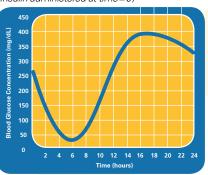
(Insulin administered at time=0)



Action: Decrease SID dose by 25% and administer insulin twice daily or change to longer-acting preparation

Insulin-induced Hyperglycemia or Somogyi Effect

(Insulin administered at time=0)



Action: For dogs, decrease dose by 50% or more. You may need to go back to the starting dose if the current dose is higher than 2.2 IU/kg. For cats, decrease dose by 50% or return to starting dose of 1 IU/cat BID

CAUSES OF INSULIN RESISTANCE.

Some causes of insulin resistance can be detected immediately. However, identification of many other causes of insulin resistance may require an extensive round of diagnostic tests. Several concurrent disorders can affect insulin status in dogs and cats and interfere with the effectiveness of insulin therapy.

DIAGNOSTIC TESTS TO CONSIDER FOR THE EVALUATION OF INSULIN RESISTANCE IN DIABETIC DOGS AND CATS¹

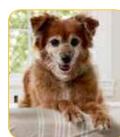
- CBC, serum biochemistry panel, urinalysis
- Bacterial culture of the urine
- Serum lipase and amylase (pancreatitis)
- Serum trypsin-like immunoreactivity (exocrine pancreatic insufficiency, pancreatitis)
- Adrenocortical function tests
- ACTH stimulation test (hyperadrenocorticism)
- Low-dose dexamethasone suppression test (hyperadrenocorticism)
- Thyroid function tests
- Baseline serum total and free T₄ (hypothyroidism or hyperthyroidism)
- Endogenous TSH (hypothyroidism)
- TSH stimulation test (hypothyroidism)
- TRH stimulation test (hypothyroidism or hyperthyroidism)
- T₂ suppression test (hyperthyroidism)
- Serum progesterone concentration (diestrus in intact female dog)
- Plasma growth hormone or serum insulin-like growth factor I concentration (acromegaly)
- Serum insulin concentration 24 hours after discontinuation of insulin therapy (insulin antibodies)
- Serum triglyceride concentration (hyperlipidemia)
- Abdominal ultrasonography (adrenomegaly, adrenal mass, pancreatitis, pancreatic mass)
- Thoracic radiography (cardiomegaly, neoplasia)
- MRI (pituitary mass)

REFERENCES:

1. Feldman EC, Nelson RW. Canine and Feline Endocrinology and Reproduction, 3rd ed. St. Louis, MO: Saunders; 2004:526. 2. Feldman EC. Diabetes remission in cats: which insulin is best? Compend Contin Educ Vet. 2009;31(7 Suppl A).

QUESTIONS? WE'RE HERE FOR YOU.

For support and answers from Merck Animal Health diabetes professionals, call 800-224-5318. Or visit us online at www.vetsulin.com.



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GLUCOSE CURVE WORKSHEET

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vetsulin®

Intervet/Merck Animal Health

(porcine insulin zinc suspension) NADA 141-236, Approved by FDA

CALITION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

vetsulin® is a sterile aqueous zinc suspension of purified porcine insulin. Fach ml_contains:

| purified porcine insulin (35% amorphous and 65% crystalline) | 40 IU |
|--|---------|
| Zinc (as chloride) | 0.08 mg |
| Sodium acetate trihydrate | 1.36 mg |
| Sodium chloride | 7.0 mg |
| Methylparaben (preservative) | 1.0 mg |

pH is adjusted with hydrochloric acid and/or sodium hydroxide.

INDICATION

vetsulin® (porcine insulin zinc suspension) is indicated for the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs and cats with diabetes mellitus.

DOSAGE AND ADMINISTRATION

FOR SUBCUTANEOUS INJECTION IN DOGS AND CATS ONLY

Vials: USE OF A SYRINGE OTHER THAN A U-40 SYRINGE WILL RESULT IN INCORRECT DOSING. Shake the vial thoroughly until a homogeneous, uniformly milky suspension is obtained. Foam on the surface of the suspension formed during shaking should be allowed to disperse before the product is used and, if required, the product should be gently mixed to maintain a homogeneous, uniformly milky suspension before use. Clumps or white particles can form in insulin suspensions: do not use the product if visible clumps or white particles persist after shaking thoroughly.

<u>Cartridges:</u> VETSULIN® CARTRIDGES SHOULD BE USED EXCLUSIVELY WITH VETPEN™ AND 29G/12 MM PEN NEEDLES. Prior to loading vetsulin® cartridges, shake the cartridge until a homogeneous, uniformly milky suspension is obtained. Clumps or white particles can form in insulin suspensions: do not use the product if visible clumps or white particles persist after shaking.

The detailed instructions for use provided with VetPen™ should be strictly followed.

The injection should be administered subcutaneously, 2 to 5 cm (3/4 to 2 in) from the dorsal midline, varying from behind the scapulae to the mid-lumbar region and alternating sides.

Always provide the Owner Information Sheet with each prescription.

Dogs

The initial recommended vetsulin® dose is 0.5 IU insulin/kg body weight. Initially, this dose should be given once daily concurrently with, or right after a meal.

Twice daily therapy should be initiated if the duration of insulin action is determined to be inadequate. If twice daily treatment is initiated, the two doses should each be 25% less than the once daily dose required to attain an acceptable nadir. For example, if a dog receiving 20 units of vetsulin® once daily has an acceptable nadir but inadequate duration of activity, the vetsulin® dose should be changed to 15 units twice daily.

The veterinarian should re-evaluate the dog at appropriate intervals and adjust the dose based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained. Further adjustments in dosage may be necessary with changes in the dog's diet, body weight, or concomitant medication, or if the dog develops concurrent infection, inflammation, neoplasia, or an additional endocrine or other medical disorder.

Cats

The initial recommended dose in cats is 1 to 2 IU per injection. The injections should be given twice daily at approximately 12 hour intervals. For cats fed twice daily, the injections should be given concurrently with, or right after each meal. For cats fed ad libitum, no change in feeding schedule is needed.

The veterinarian should re-evaluate the cat at appropriate intervals and adjust the dose based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained. Further adjustments in dosage may be necessary with changes in the cat's diet, body weight, or concomitant medication, or if the cat develops concurrent infection, inflammation, neoplasia, or an additional endocrine or other medical disorder.

CONTRAINDICATIONS

Dogs and cats known to have a systemic allergy to pork or pork products should not be treated with vetsulin®. vetsulin® is contraindicated during periods of hypoglycemia.

WARNINGS

User Safety: For use in animals only. Keep out of the reach of children. Avoid contact with eyes. In case of contact, immediately flush eyes with copious amounts of water for 15 minutes. Accidental injection may cause clinical hypoglycemia. In case of accidental injection, seek medical attention immediately. Exposure to product may induce a local or systemic allergic reaction in sensitized individuals

Animal Safety: Owners should be advised to observe for signs of hypoglycemia (see Owner Information Sheet). Use of this product, even at established doses, has been associated with hypoglycemia. An animal with signs of hypoglycemia should be treated immediately. Glucose should be given orally or intravenously as dictated by clinical signs. Insulin should be temporarily withheld and, subsequently, the dosage should be adjusted, if indicated. Any change in insulin should be made cautiously and only under a veterinarian's supervision. Changes in insulin strength, manufacturer, type, species (animal, human) or method of manufacture (rDNA versus animal-source insulin) may result in the need for a change in dosage.

Appropriate diagnostic tests should be performed to rule out endocrinopathies in pets that are difficult to regulate (e.g., hyperadrenocorticism in dogs and hyperthyroidism in cats).

PRECAUTION

Animals presenting with severe ketoacidosis, anorexia, lethargy, and/or vomiting should be stabilized with short-acting insulin and appropriate supportive therapy until their condition is stabilized. As with all insulin products, careful patient monitoring for hypoglycemia and hyperglycemia are essential to attain and maintain adequate glycemic control and prevent associated complications. Overdosage can result in profound hypoglycemia and death. Progestogens, certain endocrinopathies, and glucocorticoids can have an antagonistic effect on insulin activity. Intact bitches should be ovariohysterectomized.

Progestogen and glucocorticoid use should be avoided.

Drug Interactions:

In the US clinical effectiveness studies, dogs and cats received various medications while being treated with vetsulin® including antimicrobials, antivirals, antifungals, antihistamines, analgesics, anesthetics/tranquilizers, diuretics, bronchodilators, corticosteroids (cats), NSAIDs, thyroid hormone supplementation, hyperthyroid medication (methimazole), internal and external parasiticides, anti-emetics, dermatological topical treatments and oral supplements, ophthalmic preparations containing antimicrobials and antiinflammatories, and various vaccines. No medication interactions were reported. This drug was not studied in dogs receiving corticosteroids.

Reproductive Safety: The safety and effectiveness of vetsulin® in breeding, pregnant, and lactating dogs and cats has not been evaluated.

Use in puppies and kittens: The safety and effectiveness of vetsulin® in puppies and kittens has not been evaluated.

ADVERSE REACTIONS

Dogs

In the field effectiveness and safety study, 66 dogs were treated with vetsulin®. Sixty-two dogs were included in the assessment of safety. Hypoglycemia (defined as blood glucose < 50 mg/dL) with or without associated clinical signs occurred in 35.5% (22/62) of the dogs at various times during the study. Clinical signs of hypoglycemia were generally mild in nature (described as weakness, lethargy, stumbling, falling down, and/or depression). Disorientation and collapse were reported less frequently and occurred in 16.1% (10/62) of the dogs. Two dogs had a seizure and one dog died during the seizure. Although never confirmed, the presumptive diagnosis was hypoglycemia-induced seizures. In the rest of the dogs, hypoglycemia resolved with appropriate therapy and adjustments in insulin dosage. Seven owners recorded the following observations about the injection site on the home monitoring forms: swollen, painful, sore, and a bleb under the

The following clinical observations occurred in the field study following treatment with vetsulin® and may be directly attributed to the drug or may be secondary to the diabetic state or other underlying conditions in the dogs: hematuria, vomiting, diarrhea, pancreatitis, non-specific hepatopathy/pancreatitis, development of cataracts, and urinary tract infections.

In a 21-day field safety and effectiveness study, 40 dogs, already well controlled on vetsulin®, were administered vetsulin® using a VetPen™ insulin pen loaded with a pre-filled 2.7 mL vetsulin® cartridge and 29 gauge/12 mm pen needles. All dogs enrolled in the study were evaluated for safety. Loss of diabetic control was reported in 10 dogs, 3 of which were withdrawn from the study. Four dogs' loss of control resolved after dose adjustment while still using the insulin pen. For the remaining 3 dogs, the loss of diabetic control was reported at the end of the study and outcome was not documented. Two dogs had injection site reactions: edema in one dog and two instances of crusting in another. Poor appetite and weight loss was reported in one dog.

ats

In a field effectiveness and safety study, safety data was reported for 78 cats receiving vetsulin®. Hypoglycemia (defined as blood glucose < 50 mg/dL) was reported in 61 cats (88 total incidences). Fifteen of the occurrences (involving 13 cats) were associated with clinical signs described as lethargy, diarrhea, decreased appetite/anorexia, vomiting, and hypothermia. One cat had seizures following accidental overdosing by the owner and again during the subsequent dose adjustment period. The cat responded to supportive therapy and had no further hypoglycemic episodes. In all cases of hypoglycemia, the clinical signs resolved following symptomatic treatment and/or dose adjustment. Polyneuropathy was reported in 4 cats. Two injection site reactions were reported: one as a mildly thickened subcutaneous tissue reaction and the second as a mild bruising.

The following clinical observations occurred in the field study following treatment with vetsulin® and may be directly attributed to the drug or may be secondary to the diabetic state or other underlying conditions in the cats: vomiting, lethargy, diarrhea, decreased appetite/anorexia, pancreatitis, dermal events, respiratory disease, urinary tract disorder, renal disease, dehydration, weight loss, polydipsia, polyuria, behavioral change, and ocular discharge/conjunctivitis. In a smaller field effectiveness and safety study, 14 cats were treated with vetsulin®. Hypoglycemia was reported in 6 cats (8 total occurrences). Lethargy not associated with hypoglycemia was reported in 4 cats (6 total occurrences). The following clinical observations occurred in the field study following treatment with vetsulin® and may be directly attributed to the drug or may be secondary to the diabetic state or other underlying conditions in the cats: foul odor to stool, diarrhea, dull coat, rapid, shallow breathing, stiff gate in rear, gallop rhythm, and pruritus with

During the 1998-2007 period, the following adverse events in 50 cats treated with porcine insulin zinc suspension were reported to Intervet International and Intervet Inc: Death, seizures, lack of effectiveness/dysregulation, hypoglycemia, allergic or skin reaction, lethargy, vomiting/diarrhea, injection pain, hyperthermia, nystagmus, PU/PD, and abnormal behavior.

In a 21-day field safety and effectiveness study, 36 cats, already well controlled on vetsulin®, were administered vetsulin® using a VetPen™ insulin pen loaded with a pre-filled 2.7 mL vetsulin® cartridge and 29 gauge/12 mm pen needles. Loss of diabetic control was reported in three cats all of which resolved after dose adjustment while still using the insulin pen. Hypoglycemia was reported in one cat. The cat recovered with supportive care and dose adjustment.

To report suspected adverse drug experiences, call Merck at 1-800-224-5318.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or https://www.fda.gov/AnimalVeterinary/SafetyHealth

GENERAL PHARMACOLOGY

vetsulin® is a mixture of amorphous and crystalline insulin resulting in immediate and prolonged insulin activity. In dogs, vetsulin® may show two peaks of activity. In a laboratory study, 12 healthy adult Beagles were administered vetsulin® at a dose of 0.5 IU/kg. The onset of activity varied from 0.5 to 2 hours; the time to peak activity varied from 1 to 10 hours; and the duration of activity varied from 10 to 24 hours. In diabetic dogs, vetsulin® has two peaks of activity following subcutaneous administration (the first occurs at 2 to 6 hours and the second at 8 to 14 hours). The duration of activity varies between 14 and 24 hours.

In cats, vetsulin® has a single peak of activity. In a laboratory study, 12 healthy adult cats were administered vetsulin® at a dose of 0.5 IU/kg. The onset of activity varied from 0.5 to 2 hours; the time to peak activity varied from 2 to 6 hours; and the duration of activity varied from 8 to 24 hours. In diabetic cats, the peak activity following subcutaneous administration of vetsulin® occurs between 1.5 and 8 hours, and the duration of activity varies between 8 and 12 hours.

The peak(s) of activity, duration of activity, and dose required to adequately control diabetic signs vary between individuals and may vary in the same individual from day to day. The time ranges should only be considered as initial guidelines.

EFFECTIVENESS

Dogs

A total of 66 client-owned dogs were enrolled in and 53 completed the effectiveness and safety field study. The dogs completing the study included 22 breeds of purebred and various mixed breed dogs ranging in age from 4.8 to 14 years, and ranging in weight from 4.2 to 51.3 kg. Of the dogs completing the study, 25 were spayed females and 28 were male (21 neutered and 7 intact).

Dogs were started on vetsulin® at a dose of 1 IU/kg plus a body weight-dependent dose supplement once daily. The initial treatment time to reach acceptable glycemic control (Dose determination period) ranged from 5 to 151 days. Dogs were evaluated for treatment effectiveness three times at 30-day intervals (Study Period). The blood glucose curve means and mean nadirs were compared pre- and post-treatment to assess effectiveness. Glycemic control was considered adequate if an acceptable blood glucose curve was achieved (reduction in hyperglycemia and a nadir of 60 - 160 mg/dL), clinical signs of hyperglycemia (polyuria, polydipsia, and ketonuria) were improved, and hypoglycemia (blood glucose < 50 mg/dL) was avoided. The blood glucose curve mean was reduced from 370 mg/dL pre-treatment to 151 mg/dL, 185 mg/dL, and 184 mg/dL at the

three treatment period evaluations. The blood glucose mean nadir was reduced from 315 mg/dL pre-treatment to 93 mg/dL, 120 mg/dL, and 119 mg/dL at the three treatment period evaluations. Sixty days after an adequate vetsulin® dose was initially established, 94%, 96% and 83% of study dogs experienced a reduction in polyuria, polydipsia, and ketonuria, respectively. Investigators reported adequate glycemic control an average of 81% of the time during the Study Period.

In a 21-day field safety and effectiveness study, 40 dogs, already well controlled on vetsulin®, were administered vetsulin® using a VetPen™ insulin pen loaded with a pre-filled 2.7 mL vetsulin® cartridge and 29 gauge/12 mm pen needles. Thirty-eight of 40 dogs were evaluated for effectiveness. Thirty-srow of the 38 owners (97.4%) said they were able to learn how to use the pen. Thirty-five of the 38 owners (92.1%) said the pen was well tolerated by the dogs. For 34 of the 38 dogs (89.5%), the investigators said that the diabetes was not negatively affected by the use of the pen.

Cats

A total of 85 client-owned cats (53 males and 25 females-all neutered) of various breeds were enrolled in a 60 day field effectiveness and safety study with continued use up to Day 180. Seven cats were removed from the study prior to the Day 7 evaluation. The remaining cats ranged in age from 3 to 17.5 years and in weight from 1.9 to 10.8 kg. Seventy-two cats completed the study to Day 60 and 66 cats completed to Day 180. The cats were started on vetsulin® at an initial dose of 1 to 2 IU insulin twice daily. Scheduled evaluations occurred at Days 7, 14, 30, 60, and 180. Dose adjustments were allowed at and between the evaluations. Effectiveness was based on blood glucose curve mean, blood glucose nadir and improvement in clinical signs. Blood glucose curve means decreased from 394 mg/dL on Day 0 to 217 mg/dL on Day 60. The mean blood glucose nadir decreased from 343 mg/dL on Day 0 to 146 mg/dL on Day 60. Fourteen client-owned cats (10 males and 4 females-all neutered) of various breeds were enrolled in a 60 day effectiveness and safety field study. The cats ranged in age from 5 to 14 years and in weight from 3.40 to 6.97 kg. Twelve cats completed the study. The cats were started on vetsulin® at an initial dose of 1 to 2 IU insulin twice daily. Scheduled evaluations occurred at Days 7, 14, 30, and 60. Dose adjustments were allowed at and between the evaluations. The blood glucose curve means decreased from 354 mg/ dL on Day 0 to 162 mg/dL on Day 60. The mean blood glucose nadir decreased from 321 mg/dL on Day 0 to 99 mg/dL on Day 60.

In a 21-day field safety and effectiveness study, 36 cats, already well controlled on vetsulin®, were administered vetsulin® using a VetPen™ insulin pen loaded with a pre-filled 2.7 mL vetsulin® cartridge and 29 gauge/12 mm pen needles. Thirty-six owners (100%) said they were able to learn how to use the pen. Thirty-four owners (94.4%) said the pen was well tolerated by the cats. For thirty-five cats (97.2%), the investigators said that the diabetes was not negatively affected by the use of the pen.

HOW SUPPLIE

vetsulin® is supplied as a sterile injectable suspension in multidose vials containing 10 mL of 40 IU/mL porcine insulin zinc suspension or in multidose cartridges containing 2.7 mL of 40 IU/mL porcine insulin zinc suspension. Vials are supplied in cartons of one, 10 mL vial. Cartridges are supplied in cartons of 10, 2.7 mL cartridges.

STORAGE CONDITIONS

Store in an upright position under refrigeration at 2°C to 8°C (36°F to 46°F). Do not freeze. Protect from light. The loaded VetPen^{IM} can be stored on its side.

Use contents within 42 days of first puncture.

Additional information about vetsulin®, VetPen™, and diabetes mellitus can be found at www. vetsulin com

Distributed by: Intervet Inc (d/b/a Merck Animal Health), Madison, NJ 07940

Made in Germany

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Take advantage of useful pet diabetes management and support items for your clinic and pet parents:

- www.vetsulin.com
- www.usa.petdiabetesmonth.com
- Training Videos
- Glucose Curve Worksheets
- Pet Diabetes Tracker App
- Sugar & Spike



The **Pet Diabetes Tracker** is a free app that helps pet owners manage their pet's diabetes on their smartphone or tablet. Owners can track the amount of insulin given and also set reminders for when the next dose is needed. They can even reorder insulin directly through the app to ensure they never miss a dose.

Your patients can download the Pet Diabetes Tracker from online app stores.

