Bexacat™
(bexagliflozin tablets)

The search for a non-insulin alternative is over.

INSULIN FREE

Give cats the once-daily tablet that provides effective glycemic control.

INDICATION Bexacat is indicated to improve glycemic control in otherwise healthy cats with diabetes mellitus not previously treated with insulin.

IMPORTANT SAFETY INFORMATION Before using this product, it is important to read the entire product insert, including the boxed warning. See accompanying label for full prescribing information.

Elanco™

Bexacat™ (bexagliflozin tablets) is the FIRST and ONLY non-insulin oral treatment specifically designed for feline diabetes in otherwise healthy cats not previously treated with insulin.

BREAKTHROUGH SGLT2 INHIBITOR

Innovative sodium-glucose cotransporter 2 (SGLT2) inhibitor provides effective glycemic control without injections

EFFECTIVE GLYCEMIC CONTROL

Decreases average blood glucose concentration by over 70% in just 8 hours[1] with minimal risk of hypoglycemia

ONE TABLET ONCE A DAY

Convenient, needle-free, once-daily tablet dosed independently of patient weight ensures dosing accuracy*

*Approved for cats weighing 6.6 lbs. (3.0 kg) or greater.

IMPORTANT SAFETY INFORMATION: Cats treated with Bexacat may be at an increased risk of diabetic ketoacidosis or euglycemic diabetic ketoacidosis, both of which may result in death. As diabetic ketoacidosis and euglycemic diabetic ketoacidosis in cats treated with Bexacat may result in death, development of these conditions should be treated promptly, including insulin administration and discontinuation of Bexacat.

IMPORTANT SAFETY INFORMATION: Do not use Bexacat in cats with diabetes mellitus who have previously been treated with insulin, who are receiving insulin, or in cats with insulin-dependent diabetes mellitus. The use of Bexacat in cats with insulin-dependent diabetes mellitus, or the withdrawal of insulin and initiation of Bexacat, is associated with an increased risk of diabetic ketoacidosis or euglycemic diabetic ketoacidosis and death.

The challenge of treating feline diabetes.

Feline diabetes mellitus (DM) is a common chronic illness that requires continuing, lifelong medical care and owner education to prevent complications and ensure good quality of life.[2]

Successful treatment depends on close owner observation of clinical signs and periodic evaluation by a veterinarian.[2]

Traditionally, insulin injections have been the only way to manage diabetes in cats.

LESS THAN HALF COMPLY

Less than half of cat owners comply with proper daily insulin treatment.[1]

Potential treatment failure is high.

Pet owner compliance, costs and impact on lifestyle all contribute to potential treatment failure in diabetic cats.[3]

Unfortunately, these challenges can lead to owners electing euthanasia.

Treating feline diabetes can be frustrating for pet owners.

It can take weeks to find the optimal dosage.

Insulin requires refrigeration.

The majority of cats must be given injections twice per day.[4]

Dosing errors can occur, which can result in hypoglycemia.

On average

1 IN 10

diabetic pets are euthanized at diagnosis.[3]

Compliance presents further challenges for pet owners:

88% FIND IT INTERFERES WITH SCHEDULE

88% of pet owners find that the dosing schedule interferes with their daily routine.[1]

62% FIND IT DIFFICULT

62% of pet owners find it too difficult to administer treatment or have an uncooperative cat.[1]

An additional

1 IN 10

were euthanized within a year of treatment because of lack of success or compliance.[3]

IMPORTANT SAFETY INFORMATION: Bexacat™ (bexagliflozin tablets) should not be initiated in cats with: Anorexia, dehydration, or lethargy at the time of diagnosis of diabetes mellitus, as it may indicate the presence of other concurrent disease and increase the risk of diabetic ketoacidosis.

A feline pancreatic lipase (fPL) level > 5.3 mcg/L, diagnostic imaging consistent with pancreatitis, a history of pancreatitis, or current clinical signs suggestive of pancreatitis.

Discover the needle-free diabetes treatment made for cats.

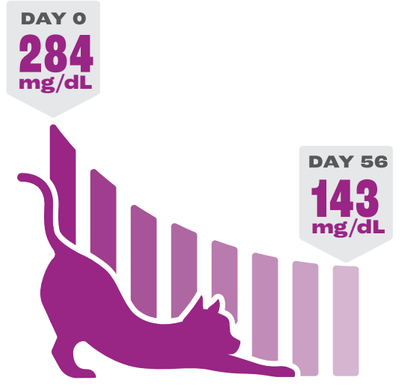
How Bexacat™ (bexagliflozin tablets) works

Bexacat is a sodium-glucose cotransporter 2 (SGLT2) inhibitor. SGLT2 is the primary transporter responsible for reabsorption of glucose from the glomerular filtrate back into the circulation.

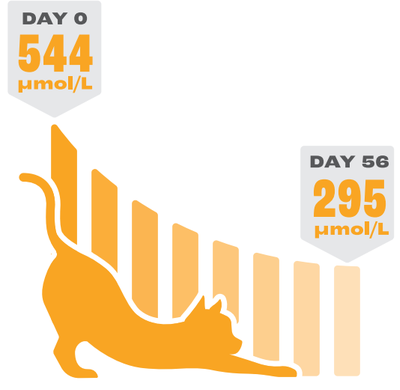
- By inhibiting SGLT2, Bexacat reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, increasing urinary glucose excretion.
- This increase in glucose excretion through the urine, in turn, lowers the plasma glucose concentration in the blood.

Give cats the once-daily tablet alternative that provides effective glycemic control

Mean Blood Glucose Curve



Fructosamine Levels



Treatment Success

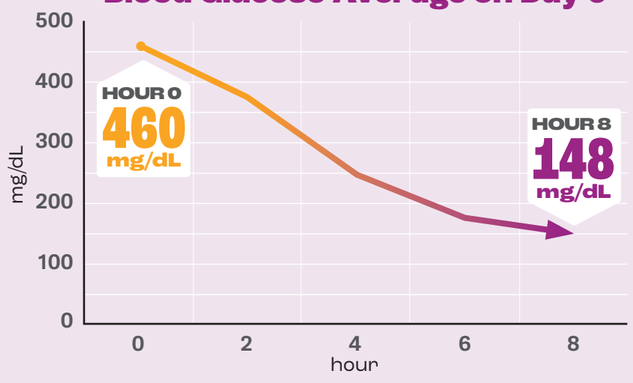
83.1% OF CATS WERE CONSIDERED TREATMENT SUCCESSES AT DAY 56*

>85% OF CATS WERE CONSIDERED TREATMENT SUCCESSES AT DAY 728**

Backed by efficacy

In a series of multicenter field studies, Bexacat was proven to be effective at improving glycemic control in cats.

Blood Glucose Average on Day 0



Percentage of cats with improvements in clinical signs by Day 56*

68.0% CATS IMPROVED IN **POLYURIA**

74.0% CATS IMPROVED IN **POLYDIPSIA**

57.1% CATS IMPROVED IN **POLYPHAGIA**

54.6% CATS IMPROVED IN **BODY WEIGHT**

IMPORTANT SAFETY INFORMATION: Sudden onset of hyporexia/anorexia, lethargy, dehydration, or weight loss in cats receiving Bexacat should prompt immediate discontinuation of Bexacat and assessment for diabetic ketoacidosis, regardless of blood glucose level.

*In a 180-day multicenter field effectiveness and safety study.
**In an extended use study of cats previously treated with bexagliflozin.

IMPORTANT SAFETY INFORMATION: Persistent plasma bexaglifozin blood levels, increased serum calcium, and the long-term use of Bexacat may increase the risk or urothelial carcinoma.

Target Animal Safety Study

In a well-controlled laboratory margin of safety study of healthy, non-diabetic cats, Bexacat™ (bexagliflozin tablets) was administered orally to 28 fasted, lean, intact adult cats at doses of at least 1X (eight cats), 3X (eight cats) and 5X (12 cats) the maximum exposure dose (5 mg/kg) once daily for 26 weeks.

Polyuria, glucosuria (with a corresponding increase in food consumption), loose stools, diarrhea and ketonuria were reported more frequently in cats that received Bexacat than in control cats.

There were drug-related clinically insignificant increases in calcium, magnesium and cholesterol levels as well as decreases in creatinine and amylase levels, blood pressure and heart rate values.

Gross necropsy demonstrated treatment-related observations of mild, diffuse zonal patterns in the liver in the 5X group.

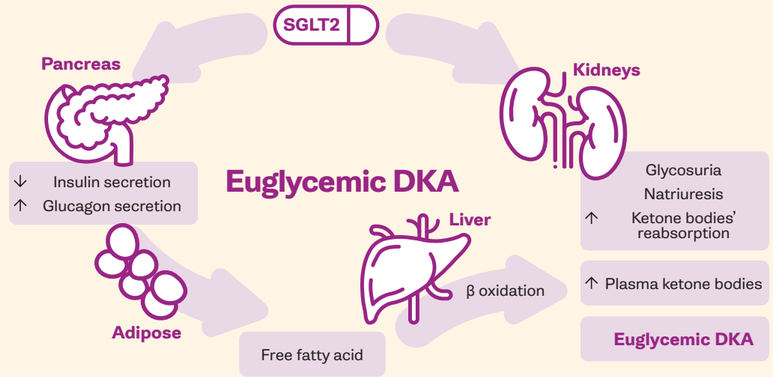
There were no clinically relevant drug-related effects on hematology and coagulation parameters and organ weight values.

The potential for diabetic ketoacidosis (DKA) and euglycemic diabetic ketoacidosis (eDKA).

Cats treated with Bexacat may be at an increased risk of developing DKA or eDKA, which can be life threatening if not treated appropriately.

eDKA is DKA that occurs with a normal blood glucose concentration:

- eDKA occurs almost exclusively in patients treated with an SGLT2 inhibitor
- It is unlikely to have been seen in practice previously
- Insulin administration is critical to these patients, despite normoglycemia



How to respond to DKA and eDKA diagnosis

If cats are anorexic, lethargic, dehydrated or losing weight, measure Beta-hydroxybutyrate (BHBA). If DKA or eDKA is discovered:

- Discontinue Bexacat treatment immediately
- Treat with insulin (even if euglycemic)
- Supplement with intravenous dextrose
- Provide nutritional support to prevent or treat hepatic lipidosis.

Due to the risk of developing DKA or eDKA, do not use Bexacat in cats with diabetes mellitus who have previously been treated with insulin, who are receiving insulin, or in cats with insulin-dependent diabetes mellitus.

IMPORTANT SAFETY INFORMATION: See Animal Safety Warnings and Precautions for other important criteria and screening tests prior to initiating treatment with Bexacat. Discontinue Bexacat and contact a veterinarian immediately if the cat develops anorexia, lethargy, vomiting, diarrhea, or weakness.

Improve compliance with convenience.

Bexacat™ (bexagliflozin tablets) is a convenient, needle-free, once-daily flavored tablet dosed independently of patient weight that helps ensure dosing accuracy.*

No dose titration needed

Can be given with food for convenient administration

No refrigeration required

*Approved for cats weighing 6.6 lbs. (3.0 kg) or greater.

Patient Selection

Once newly diagnosed with DM, a patient may be considered eligible for Bexacat provided:

Cat is clinically well

- Normal hydration
- Not lethargic
- Eating well

No significant disease

Baseline blood work shows no significant renal or hepatic disease, DKA or pancreatitis.

- BHBA < 37 mg/dL (or < 25 mg/dL if history of renal disease or metabolic acidosis)
- No other lab values consistent with DKA
- No evidence suggesting pancreatitis, including clinical signs, diagnostic imaging or feline pancreas-specific lipase (fPL) > 5.3 mcg/L

Has not been treated with insulin previously

Bexacat should not be initiated in cats with:

- Laboratory values consistent with diabetic ketoacidosis, including elevated urine or serum ketones, and metabolic acidosis (high anion gap, or decreased bicarbonate, pH, or partial pressure carbon dioxide [PaCO2] levels).
- A BHBA > 37 mg/dL, or if BHBA is > 25 mg/dL and the cat has a history of renal disease or metabolic acidosis.

IMPORTANT SAFETY INFORMATION: Cats treated with Bexacat may be at an increased risk of diabetic ketoacidosis or euglycemic diabetic ketoacidosis, both of which may result in death.

Monitoring Guidelines

Time After Start of Treatment	Recommended Monitoring	Action
3-5 days	• Physical exam, including weight • BHBA level	• **Continue Bexacat** unless cat is losing weight or BHBA is not decreasing, then discontinue Bexacat and transition to insulin • Recheck at the two-week time point
2 weeks	• Physical exam, including weight • BHBA level • Glucose curve and fructosamine	• **Continue Bexacat** unless cat is losing weight or if BHBA is rising, then discontinue Bexacat and transition to insulin • If average blood glucose (BG) from an 8-hour curve ≥ 250mg/dL and/or serum fructosamine is above reference range, monitor closely • Recheck in two weeks
4 weeks	• Physical exam, including weight • BHBA level • Glucose curve and fructosamine	• **Continue Bexacat** unless cat is losing weight or if BHBA is rising, then discontinue Bexacat and transition to insulin • If average BG from an 8-hour curve ≥ 250mg/dL and/or serum fructosamine is above reference range, monitor closely • Recheck in four weeks
8 weeks	• Physical exam, including weight • BHBA level • Glucose curve and fructosamine	• **Continue Bexacat** unless cat is losing weight or if BHBA is rising, then discontinue Bexacat and transition to insulin • If average BG from an 8-hour curve ≥ 250mg/dL and/or serum fructosamine is above reference range, transition to insulin • Recheck every 90 days or as medically indicated

IMPORTANT SAFETY INFORMATION: See Animal Safety Warnings and Precautions for other important criteria and screening tests prior to initiating treatment with Bexacat. Discontinue Bexacat and contact a veterinarian immediately if the cat develops anorexia, lethargy, vomiting, diarrhea, or weakness.

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Sudden onset of hyporexia/anorexia, lethargy, dehydration or weight loss in cats receiving Bexacat should prompt immediate discontinuation of Bexacat and assessment for diabetic ketoacidosis, regardless of blood glucose level.

Cats demonstrating poor glycemic control, including weight loss, an average blood glucose concentration from an 8-hour blood glucose curve ≥ 250 mg/dL and/or a fructosamine above reference range should be closely monitored. If poor glycemic control exists by Week 8, discontinue Bexacat and initiate insulin.

[1]Elanco Animal Health. Data on file.
[2]Aptekmann K, Armstrong J, Coradini M, et al. Owner experiences in treating dogs and cats diagnosed with diabetes mellitus in the United States. J Am Anim Hosp Assoc. 2014. 2014;50(4):247-253.
[3]Niessen S, Hazuchova K, Powney S, et al. The big pet diabetes survey: perceived frequency and triggers for euthanasia. Vet Sci. 2017;4(27):1-13.
[4]Behrend E, Holford A, Lathan P, et al. 2018 AAHA diabetes management guidelines for dogs and cats. J Am Anim Hosp Assoc. 2022. Accessed online https://www.aaha.org/aaha-guidelines/diabetes-management/diabetes-management-home/ November 6, 2022.

NOTES

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INSULIN FREE

Provides effective glycemic control without injections

FELINE FRIENDLY

Minimal risk of hypoglycemia and no dosage changes during treatment

ONE TABLET ONCE A DAY

Convenient, needle-free, once-daily tablet dosed independently of patient weight ensures dosing accuracy*

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