

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bexatil 15 mg tablets for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: 15 mg bexagliflozin

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Microcrystalline cellulose
Starch pregelatinized
Silica colloidal anhydrous
Magnesium stearate
Flavor PAL X1212 (chicken liver, beef flavour, yeast, soya sauce powder)

Pentagonal, light brown biconvex tablets with white, brown or tan speckles.

3. CLINICAL INFORMATION

3.1 Target species

Cats

3.2 Indications for use for each target species

For the reduction of hyperglycaemia and to improve hyperglycaemia-associated clinical signs in cats with non-insulin-dependent diabetes mellitus.

3.3 Contraindications

Do not use in cats that have recently been treated with insulin or are receiving insulin or in cats with insulin-dependent diabetes mellitus.

Do not transfer cats receiving insulin treatment for diabetes mellitus onto this product (see also section 4.2 Pharmacodynamics).

Do not use in cats with diabetic ketoacidosis, euglycaemic diabetic ketoacidosis, diabetic ketonuria or severe dehydration requiring intravenous fluid supplementation.

Do not use in cats with end-stage renal failure as these cats are unlikely to respond to treatment and will be at high risk of serious events such as diabetic ketoacidosis (DKA).

Do not use in cases of hypersensitivity to the active substance or to any of the excipient(s).

3.4 Special warnings

The product should not be used in combination with insulin (see section 3.3 Contraindications). The safety and efficacy of a combined treatment with bexagliflozin and other blood glucose-lowering treatments has not been evaluated and may increase the risk for symptomatic hypoglycaemia. Therefore, combined treatment is not recommended.

Asymptomatic hypoglycaemia based on single blood glucose measurements may be observed sporadically with bexagliflozin treatment.

Based on the mode of action, it is expected that cats being treated with SGLT2 inhibitors will exhibit glucosuria. Therefore, the degree of glucosuria is not a reliable diagnostic indicator for monitoring glycaemic control. As glucosuria may persist after discontinuation of the veterinary medicinal product, blood glucose concentrations should be monitored to determine when diabetic treatment needs to be resumed.

Diabetic remission following bexagliflozin treatment was not investigated in the clinical field trials. Due to the mode of action of bexagliflozin, it may be difficult to identify cats which are in remission. If remission is suspected, consideration could be given to withdrawing treatment but continuing other measures (e.g. low-carbohydrate diet, appropriate weight management) and closely monitoring glycaemic control and for return of clinical signs. If the cat relapses, then bexagliflozin treatment can be restarted.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Based on the mode of action of SGLT2 inhibitors (such as bexagliflozin), adequate endogenous insulin production is a requirement for successful management of diabetes mellitus with this veterinary medicinal product.

Since there is no established threshold for endogenous insulin to conclude on sufficient availability, the following instructions are important to identify cats suitable for treatment initiation: **screening and initial monitoring.**

During field efficacy and safety studies, the youngest cat administered the product was three years of age and the lowest bodyweight was 2.8 kg. Use of this veterinary medicinal product in cats younger than 3 years of age or less than 2.8 kg bodyweight should be based on a benefit/risk assessment by the responsible veterinarian.

The safety and efficacy of the product has not been fully evaluated in severe cases of renal/liver/cardiac disease or investigated in cats with heart failure, hyperthyroidism (elevated total T4 serum levels), uncontrolled elevated blood pressure, neoplasia, a history of feline idiopathic cystitis, acromegaly or major infection processes. Use only according to the benefit/risk assessment by the responsible veterinarian.

The safety and efficacy of the product has not been investigated in cats with beta-hydroxybutyrate >3.6 mmol/L (>37.0 mg/dL) or in cats with beta-hydroxybutyrate >2.4 mmol/L but < 3.6 mmol/L (>25.0 mg/dL but <37.0 mg/dL) with a history of renal disease or acidosis.

Chronic diarrhoea and associated dehydration should be resolved prior to initiation of treatment; treatment should be discontinued in cats with diarrhoea that is persistent and unresponsive to conventional therapy.

Use with caution in cats suffering from pre-existing hepatic or renal disease.
Use with caution in cats with elevated calcium levels.
Use with caution in cats that have a poor appetite, dehydration or lethargy.

Use with caution in cats with elevated feline pancreatic lipase levels. Treatment should not be initiated in cats with a history of pancreatitis and feline pancreatic lipase values greater than 5.3 µg/L. Cases of clinical pancreatitis should be resolved prior to initiation of treatment with bexagliflozin.

Cats with co-morbidities such as hepatic disease, infectious disease, cardiac disease, elevated blood pressure, feline idiopathic cystitis, renal insufficiency (IRIS stage 3 or 4), neoplasia and hyperthyroidism were excluded from clinical trials. Safety and efficacy of the veterinary medicinal product in diabetic cats with these co-morbidities has not been fully investigated. Use of the veterinary medicinal product in cats with co-morbidities is only according to the benefit-risk assessment by the prescribing veterinarian.

Cats should be evaluated for concurrent diseases that may predispose to DKA (e.g. acromegaly).

Suspected or confirmed DKA, cachexia or dehydration should be resolved prior to treatment.

Screening and initial monitoring

Screening for DKA must be performed prior to treatment start. Treatment should not be initiated, or resumed, if ketone bodies at concentrations indicative of DKA are present. Clinical signs such as unintended or persistent weight loss, acute vomiting, dehydration, lethargy and anorexia (inappetence) may indicate DKA or a higher risk of developing DKA. Cats considered to be at risk of developing DKA need close monitoring and alternative treatment plans should be considered. The risk of developing DKA decreases after the first two weeks of treatment, but DKA may occur at any time (for monitoring see below). If treatment start is delayed for more than four days after diagnosis of diabetes mellitus, the veterinarian should re-assess the risk for DKA. Check for ketones every 1 to 3 days for the first two weeks of treatment and whenever clinical signs of illness are seen.

Routine Monitoring

Monitoring for diabetic control, DKA (including evaluation for ketone bodies in blood and/or urine) and urinary tract infections is recommended at regular intervals by a veterinarian. Discontinue treatment immediately in the event of confirmed or suspected DKA or diabetic ketonuria and investigate accordingly.

Due to the mode of action of SGLT2 inhibitors, hyperglycaemia may not be present in case of DKA (euglycaemic DKA). The diagnosis of euglycaemic DKA needs to be based on clinical signs, a laboratory finding of metabolic acidosis and other laboratory findings consistent with DKA. In case of DKA it is imperative to immediately initiate appropriate treatment, which includes prompt initiation of insulin therapy, despite normal blood glucose values in euglycaemic DKA. The initiation of insulin is needed to stop the progression of ketoacidosis.

Delay in diagnosis and treatment of diabetic ketoacidosis and euglycemic diabetic ketoacidosis may result in increased morbidity and mortality.

Cats may require temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis (e.g. anorexia or inappetence due to acute illness or fasting around surgery).

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Sodium-glucose co-transporter 2 (SGLT2) inhibitors, such as bexagliflozin, may cause hypersensitivity reactions. People with known hypersensitivity to bexagliflozin, or SGLT2 inhibitors, should avoid contact with the veterinary medicinal product. If symptoms such as a skin rash occur, seek medical advice and show the package leaflet or the label to the physician.

Accidental ingestion, particularly by children, may cause transient effects such as glucosuria (increased renal glucose excretion), vomiting and diarrhoea. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats

<p>Very common (>1 animal / 10 animals treated):</p>	<p>Vomiting¹, Diarrhoea² Urinary tract infection³ Decreased appetite, Anorexia, Dehydration⁴, Lethargy, Weight loss⁵ High pancreatic-specific lipase⁶</p>
<p>Common (1 to 10 animals / 100 animals treated):</p>	<p>Diabetic ketoacidosis (DKA)⁷ Diabetic ketonuria Pancreatitis Polyuria/Polydipsia⁸ Elevated alanine aminotransferase (ALT)⁶, Elevated aspartate aminotransferase (AST)⁶, Elevated blood urea nitrogen (BUN)⁹ Hypercalcaemia¹⁰</p>

- ¹ Usually sporadic and resolves without specific therapy. Acute or more frequent vomiting may also be a sign of other severe disease conditions and should be investigated accordingly.
- ² May be transient. Supportive treatment can help resolve gastrointestinal signs. In case treatment-related diarrhoea persists, treatment should be discontinued and alternative treatments considered. See also section 3.5.
- ³ Urinary tract infection including cystitis caused by infection: may occur as part of the underlying disease. The glucosuric effect of bexagliflozin may contribute to urinary tract infection. Standard cystitis/urinary tract infection therapy should be initiated.
- ⁴ Severe dehydration should lead to screening for DKA. Appropriate supportive fluid therapy should be given as needed. Due to the mode of action of bexagliflozin, DKA can occur in the absence of hyperglycaemia (euglycemic DKA). See also sections 3.3 and 3.5.
- ⁵ May occur as part of the underlying disease or due to the effect of bexagliflozin treatment. Persistent weight loss should lead to screening for DKA. Due to the mode of action of bexagliflozin, DKA can occur in the absence of hyperglycaemia (euglycaemic DKA). See also sections 3.3 and 3.5.
- ⁶ Increasing or persistently elevated feline pancreatic lipase or liver parameters should prompt further evaluation for pancreatitis and/or hepatic disease. Consider treatment discontinuation.
- ⁷ May be euglycaemic. In case of DKA, stop treatment and initiate insulin therapy. See also sections 3.3 and 3.5.
- ⁸ Resolves without additional treatment. May occur as part of the underlying disease or due to the osmotic effect of bexagliflozin.
- ⁹ Normally mild and does not need specific therapy.
- ¹⁰ Normally mild, with calcium levels staying close to the reference range, and does not need specific therapy. If persistent hypercalcaemia develops, cats are at increased risk of forming calcium containing uroliths; in this case, bexagliflozin treatment should be withdrawn.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or for breeding cats. Use of the product is therefore not recommended during pregnancy or lactation or in breeding cats.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For oral use.

Give one flavoured tablet daily to cats at approximately the same time each day, with or without food, and regardless of blood glucose levels.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

After administration of the veterinary medicinal product up to 5 times the recommended dose for 26 weeks to young healthy cats, polyuria, glucosuria, increased urine glucose creatinine ratio, loose faeces and increased food consumption were observed.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QA10BK08

4.2 Pharmacodynamics

Bexagliflozin is a highly selective inhibitor of the sodium-glucose co-transporter 2 (SGLT-2), which is predominantly expressed in the kidney. Bexagliflozin also has a minor inhibitory effect on the SGLT-1, which is predominantly expressed in the small intestine, but also expressed at a lower level in the kidneys. SGLT-2 is the primary transporter for the reabsorption of glucose from the urine, with around 90 % of filtered glucose reabsorbed by SGLT-2 and 10 % reabsorbed by SGLT-1. Inhibition of SGLT-2 leads to glucose elimination in the urine resulting in a decrease in elevated blood glucose levels in diabetic cats. A low level of glucose will continue to be resorbed via incomplete inhibition of SGLT-1, which reduces the risk for clinical hypoglycaemia. This minor inhibitory action on SGLT-1 can also contribute to a dose-dependent softening of stool and loose stool/diarrhoea due to the expression of SGLT-1 in the small intestine.

In a US clinical field trial, the safety and efficacy of bexagliflozin, administered orally as 15 mg bexagliflozin tablet once daily in newly diagnosed diabetic cats that had not previously received insulin treatment, was evaluated. The safety and efficacy of moving cats directly from insulin to bexagliflozin was not investigated owing to results obtained from preliminary studies (see section 3.3 Contraindications). The study design utilized baseline control with all enrolled cats receiving bexagliflozin. In this trial, 83.95 % of the cats (68 of 81) treated with bexagliflozin and included in the efficacy analysis met the requirement for treatment success on Study Day 56.

The composite variable “treatment success” was defined as improvement of at least one glycaemic control variable (mean blood glucose curve < 250 mg/dL or serum fructosamine < 358 µmol/L) and improvement in at least one clinical sign of hyperglycaemia (polyuria, polydipsia, polyphagia or body weight loss). The mean of all blood glucose curve measurements was 143.74 mg/dL (95% CI 129.17, 158.32) and the mean serum fructosamine concentration was 301.27 µmol/L (95% CI 280.35, 322.19) on Study Day 56.

Overall, 90.7% of the cats were found to have improved by at least one clinical sign of hyperglycaemia (polyuria 74.7%, polydipsia 81.3%, polyphagia 62.7%, body weight maintenance or gain 57.3%) on Study Day 56.

Most owners (86.7%) reported improved quality of life in their cats on Study Day 56. Seventy-one of the 81 cats (87.7%) completed the study as planned after 6 months of treatment.

The safety and efficacy of bexagliflozin, 15 mg tablet, once daily per cat, was further evaluated in an extended use study in cats that have successfully completed a previous study and were expected to continue to receive bexagliflozin over their life span or until the sponsor terminated the study. At approximately 56-day intervals cat assessments and glycaemic control were evaluated and treatment success was defined by a central lab serum glucose concentration between 80 and 252 mg/dL or a serum fructosamine measurement less than or equal to the laboratory reference range lower limit corresponding to good glycaemic control (Marshfield lab: ≤320 µmol/L or IDEXX lab: ≤300 µmol/L). Overall, 95.5% post-enrolment visits were classified as glycaemic successes. Furthermore, bexagliflozin was well-tolerated.

4.3 Pharmacokinetics

Following intravenous administration of bexagliflozin in healthy cats at the dose of 1 mg/kg bw, bexagliflozin exhibited a clearance rate of 363 mL/h/kg, a volume of distribution of 3.7 L/kg, and a terminal half-life of 7.8 hours.

Following a single oral dose of the product at 15 mg bexagliflozin per cat, in a fasted state, maximum plasma concentrations (C_{max}) ranged from 953 to 2710 ng/mL, achieved within 0.5 to 4 hours (T_{max}).

The area under the plasma concentration-time curve from zero to infinity (AUC_{inf}) ranged from 4600 to 12200 h*ng/mL, with a terminal half-life of 7.7 hours. The absolute oral bioavailability in the fasted state was estimated at 78 %. Exposure is decreased in the fed state. No significant differences were observed between male and female cats.

Bexagliflozin is primarily excreted in faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after first opening the immediate packaging: 90 days

5.3 Special precautions for storage

Store in the original container.

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

HDPE bottle with a child-resistant cap.

Pack sizes of 30 or 90 tablets per bottle. One bottle per cardboard box.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 52127/5051

8. DATE OF FIRST AUTHORISATION

29 August 2025

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

August 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 15 October 2025