



**Veterinary
Medicines
Directorate**

**United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY
MEDICINAL PRODUCT**

Bexatil 15 mg Tablets for Cats

Date Created: January 2026

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Bexatil 15 mg Tablets for Cats, Tablet
Applicant	Elanco GmbH Heinz-Lohmann Strasse 4 Groden D-27472 Cuxhaven Germany
Active substance	Bexagliflozin
ATC Vetcode	QA10BK08
Target species	Cats
Indication for use	For the reduction of hyperglycaemia and to improve hyperglycaemia-associated clinical signs in cats with non-insulin-dependent diabetes mellitus.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

www.gov.uk/check-animal-medicine-licensed

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Full application in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Part 1) as amended.
Date of conclusion of the procedure	15/10/2025

I. SCIENTIFIC OVERVIEW

The product was submitted for a full application for authorisation in Great Britain (GB), in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Part 1) as amended.

Bexatil 15 mg Tablets for cats each contain 15mg of bexagliflozin. The indication is for the reduction of hyperglycaemia and to improve hyperglycaemia-associated clinical signs in cats with non-insulin-dependent diabetes mellitus. The dose is one tablet daily administered to cats with or without food.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released on the market. It has been shown that the product can be safely used in the target species, any reactions observed are indicated in the SPC¹. The product is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy² of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains bexagliflozin and the excipients lactose monohydrate, microcrystalline cellulose, starch pregelatinized, silica colloidal anhydrous, magnesium stearate and flavor PAL X1212 (chicken liver, beef flavour, yeast, soya sauce powder).

The container/closure system consists of a 30ml or 60ml high-density polyethylene bottle with a polypropylene child resistant cap. The particulars of

¹ SPC – Summary of product Characteristics.

² Efficacy – The production of a desired or intended result.

the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of preservative are justified.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant regulatory guidelines.

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

The product is manufactured using conventional manufacturing techniques.

The manufacturing process has been validated using three commercial-scale, 150 kg final blend batches processed in the same manufacturing facilities, using the same process and the same equipment as intended for batches to be commercialised. All three batches fully meet the proposed quality control specifications for release testing. The results of routine and extended in-process control (IPC) testing have demonstrated that the manufacturing process is robust and consistently yields a product capable of meeting the predefined quality characteristics. Additional testing for blend and content uniformity was conducted and confirms that the manufacturing process is capable of reliably manufacturing tablets of the proposed quality.

II.C. Control of Starting Materials

The active substance bexagliflozin is an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

II.C.4. Substances of Biological Origin

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable

II.E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form.

The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product. Satisfactory validation data for the analytical methods have been provided. Batch analytical data from the proposed production sites have been provided demonstrating compliance with the specification.

Control tests on the finished product are those appropriate for the pharmaceutical form.

II.F. Stability

Stability data on the active substance has been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

This veterinary medicine does not require any special storage conditions. It should be stored in the original container.

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

Shelf life after first opening the immediate packaging: 90 days

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACOTOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Studies have been conducted/bibliographical data has been provided which show that bexagliflozin acts by selectively inhibiting 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.

The applicant has provided bibliographical data which shows that 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.

Toxicological Studies

The applicant has provided bibliographical data which show the following toxicology results:

Single Dose Toxicity

- A LOAEL (Lowest Observed Adverse Event Level) of 167 mg/kg bw/day in male and female rats. However, the test subjects had a reduced bodyweight gain and food consumption.
- A LOAEL in male and female monkeys of 669 mg/kg bw/day. In this study it was seen that there was reduced bodyweight gain and food consumption.

Repeated Dose Toxicity

- Repeated dose toxicity studies with male and female rats were conducted over 28 days and 26 weeks.
- In both 28-day studies no adverse effects were seen and a NOAEL of 6.7 mg/kg was concluded.
- In the 26-week study a NOAEL (No Observed Adverse Event Level) of 10 mg/kg was seen in both male and female rats. There were no adverse effects seen over the 26-week period.
- Repeated dose toxicity studies on monkeys were conducted over a 31-day and 39-week period.
- In the 31-day study a 2 mg/kg/day NOAEL was established with some pharmacological effects, but these effects were reversed following the stopping of the treatment.
- The 39-week study established a NOAEL of 60mg/kg where again there were some pharmacological effects, but these effects were reversed following the stopping of the treatment.

Reproductive Toxicity, including Teratogenicity

- Multiple studies on rats were carried out to see the effects on fertility, embryonic development, embryo-foetal development, pre and post-natal

development. These studies showed no adverse effects on any of the study rationale.

- A study was also carried out in rabbits where it showed that there was no effect on embryo/foetal viability, growth, or development, at any dose level.

Mutagenicity

- No mutagenicity was determined for exposure to bexagliflozin in the *in vitro* and *in vivo* studies submitted.

Carcinogenicity

- Two studies assessing the carcinogenic effect of bexagliflozin were submitted. Both studies concluded that there is no evidence of carcinogenicity after oral administration in mice and rats.

Observations in Humans

Information was provided which shows that bexagliflozin is approved and used in human medicine.

User Safety

A user risk assessment was provided in compliance with the relevant guideline.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore, the following applicant's user recommendations are appropriate:

- 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.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:

The product will only be used in non-food animals and as a result environmental exposure will be low. A Phase II ERA was not required.

IV. CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

Tolerance in the Target Species

The applicant has submitted multiple target animal tolerance studies using multiples of the recommended dose in the target species. Multiples 1x, 3x and 5x of the therapeutic marketed product containing the same active substance were used and a placebo was used as a control. All doses were orally administered daily for 26 weeks.

The primary variables assessed in this study were clinical observations, physical examinations, body weights, food consumption, clinical pathology, urinalysis, gross pathology, and histopathology (which included organ weights). Secondary variables assessed were toxicokinetic outcomes, blood glucose curves, TK sample processing, serum SDMA (symmetric dimethylarginine) and Spec fPL (specific feline pancreatic lipase) levels, systolic blood pressure, and urine glucose:creatinine ratio (UGCR).

When the primary and secondary variables were reviewed it showed that there were no substantial adverse effects when the product was orally administered up to 5 times the recommended dose.

IV.II. Clinical Documentation

Laboratory Trials

The applicant has conducted dose determination and confirmation studies to investigate the safety and efficacy of bexagliflozin tablets for the treatment of cats, newly diagnosed with diabetes mellitus (DM), to reduce hyperglycaemia and to improve hyperglycaemia-associated clinical signs. The studies were prospective, open-labelled, historically controlled and multi-site, conducted in the USA and each one was conducted to GCP standards.

Field Trials

There were four field trials carried out which looked at the safety and efficacy of bexagliflozin tablets for the treatment of cats, newly diagnosed with diabetes mellitus (DM), to reduce hyperglycaemia and to improve hyperglycaemia-associated clinical signs.

All studies were prospective, open-labelled, historically controlled and multi-site conducted in the USA and each one was conducted to GCP standards. Each cat received one tablet daily, based on the minimum body weight permitted for inclusion. In two studies the product was administered with or without food.

The studies varied in length, two studies were over an 8-week period, another was over 6-months and the final one was over 38-month period.

Each study demonstrated that the veterinary assessment of the cat's condition did not form part of the primary efficacy evaluation. However, the data does demonstrate gradual and sustained improvement in neurological signs, musculature and hair coat quality over time provide further supportive evidence of product efficacy. The results of the pivotal study, supported by the pilot and extended-use studies appear to demonstrate a good level of efficacy in line with the proposed indication.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics the benefit/risk profile of the product is favourable.

MODULE 4

POST- AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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