

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bexatil 15 mg tablets for cats

2. STATEMENT OF ACTIVE SUBSTANCES

15 mg bexagliflozin/tablet

3. PACKAGE SIZE

30 tablets

90 tablets

4. TARGET SPECIES

Cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use by:

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.


11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco 

14. MARKETING AUTHORISATION NUMBERS

Vm 52127/5051

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle 60 ml – 90 tablets}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bexatil 15 mg tablets for cats

2. STATEMENT OF ACTIVE SUBSTANCES

15 mg bexagliflozin/tablet

3. TARGET SPECIES

Cats

4. ROUTES OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use by:

7. SPECIAL STORAGE PRECAUTIONS

Store in the original container.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco logo

9. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {Bottle 40 ml – 30 tablets}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bexatil 15 mg tablets for cats

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

15 mg bexagliflozin/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 90 days.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Bexatil 15 mg tablets for cats

2. Composition

Each tablet contains 15 mg of bexagliflozin.

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

3. Target species

Cats

4. Indications for use

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

5. 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.

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).

6. Special warnings

Special warnings:

The product should not be used in combination with insulin (see section 5 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.

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.

Pregnancy and lactation:

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.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

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.

7. Adverse events

Cats

Very common (>1 animal / 10 animals treated):	Vomiting ¹ , Diarrhoea ² Urinary tract infection ³ Decreased appetite, Anorexia, Dehydration ⁴ , Lethargy, Weight loss ⁵ High pancreatic-specific lipase ⁶
Common (1 to 10 animals / 100 animals treated):	Diabetic ketoacidosis (DKA) ⁷ Diabetic ketonuria Pancreatitis Polyuria/Polydipsia ⁸ Elevated alanine aminotransferase (ALT) ⁶ , Elevated aspartate aminotransferase (AST) ⁶ , Elevated blood urea nitrogen (BUN) ⁹ Hypercalcaemia ¹⁰

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 'Special warnings'.

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 'Contraindications' and 'Special warnings'.

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 'Contraindications' and 'Special warnings'.

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 'Contraindications' and 'Special warnings'.

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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

The veterinary medicinal product can be given with or without food, and regardless of blood glucose levels.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Store in the original container.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 90 days.

Once the immediate package is opened, using the shelf-life after first opening, calculate the discard date and record in the space provided on the label.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 52127/5021

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco GmbH,
Heinz-Lohmann-Str. 4,
Groden
27472 Cuxhaven,
Germany

PV.GBR@elancoah.com

+443308221732

Manufacturer responsible for batch release:

Elanco France S.A.S., 26 rue de la Chapelle, 68330 Huningue, France

17. Other information

POM-V

Gavin Hall

Approved: 15 October 2025