**PARTICULARS TO APPEAR ON THE OUTER PACKAGE (30 ml cardboard box)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Senvelgo 15 mg/ml oral solution for cats

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

| | |
|---|---|
| Velagliflozin* | 15 mg |
| as velagliflozin L-proline $H_20$ | 20.1 mg |

*sodium-glucose co-transporter 2 (SGLT-2) inhibitor

## 3. PACKAGE SIZE

30 ml

## 4. TARGET SPECIES

Cat

## 5. INDICATION(S)

For the treatment of diabetes mellitus in cats

## 6. ROUTES OF ADMINISTRATION

Oral use

## 7. WITHDRAWAL PERIODS

Not applicable

## 8. EXPIRY DATE

Exp. {mm/yy}

Once broached, use by:

## 9. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton.

## 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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

## 14. MARKETING AUTHORISATION NUMBERS

Vm 08327/5004

## 15. BATCH NUMBER

Lot {number}

## 16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

## 17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## 18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

| |
|---|
| POM-V<br>To be supplied only on veterinary prescription |

# MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (30 ml bottle)

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Senvelgo

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

| | |
|---|---|
| Velagliflozin | 15 mg |
| as velagliflozin L-proline $H_20$ | 20.1 mg |

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yy}

## 5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

30 ml

## 6. ROUTE(S) OF ADMINISTRATION

Oral use

## 7. WITHDRAWAL PERIOD

Not applicable

## 8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

# PACKAGE LEAFLET:

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Senvelgo 15 mg/ml oral solution for cats

## 2. COMPOSITION

Each ml contains:

Active substance:

| | |
|---|---|
| Velagliflozin* | 15 mg |
| as velagliflozin L-proline $H_20$ | 20.1 mg |

Clear colourless to slightly yellow to slightly brown solution.

*sodium-glucose co-transporter 2 (SGLT-2) inhibitor

## 3. TARGET SPECIES

Cats

## 4. INDICATIONS FOR USE

For the treatment of diabetes mellitus in cats.

## 5. CONTRAINDICATIONS

Do not use in cats with evidence of diabetic ketoacidosis, diabetic ketonuria, or severe dehydration requiring i.v. fluid supplementation (see also section 6 special warning(s)).
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

## 6. SPECIAL WARNING(S)

The safety and efficacy of a combined treatment with insulin or other blood glucose lowering treatments (excluding diet) and velagliflozin in cats has not been investigated. Due to the mode of action of insulin, there is an increased risk for hypoglycaemia, therefore combined treatment is not recommended. Concomitant therapy with other antidiabetics has not been evaluated and may increase the risk for symptomatic hypoglycaemia.

In clinical trials, hypoglycaemia (defined as serum blood glucose levels below 3.5 mmol/l) was sporadically observed, although was asymptomatic and did not demonstrate a causal relationship to the product. Based on the selectivity of velagliflozin for the SGLT-2, there is no risk for symptomatic hypoglycaemia (glucose reabsorption will be balanced by the SGLT-1).
Based on the mode of action it is expected that cats being treated with SGLT-2 inhibitors will exhibit glucosuria. Therefore, the degree of glucosuria is not a reliable

diagnostic indicator for monitoring diabetic control or diabetic remission. As glucosuria may persist for 2-3 days after discontinuation of the veterinary medicinal product, blood glucose levels should be monitored to determine when diabetic treatment needs to be resumed.

Special precautions for use in animals:

The following conditions should be resolved prior to treatment start: dehydration, suspected or confirmed diabetic ketoacidosis, clinical pancreatitis, chronic diarrhoea, cachexia.

Prior to initiating treatment, screening for ketoacidosis should be performed. Clinical signs such as dehydration, lethargy, anorexia (inappetence), acute vomiting, cachexia alongside hyperglycaemia and presence of serum or urine ketone bodies may indicate that the cat has DKA or may be at higher risk of developing DKA. Insulin pre-treated cats may be at higher risk for DKA (see below).

In field studies conducted with the veterinary medicinal product 14/277 (5.1%) of the cats that had previously not received any treatment for DM developed clinical DKA whereas 8/66 (12.1%) of cats that had previously been treated with insulin developed clinical DKA. The likelihood of pancreatic beta-cell loss and insulin-dependency may be higher in insulin pre-treated cats. As a result, the withdrawal of the insulin before the start of treatment with the product may lead to a metabolic destabilisation and initiate ketogenesis. This information should be taken into account when considering transferring a cat from insulin treatment to treatment with this veterinary medicinal product.

In line with DM treatment guidelines, cats should also be evaluated for concurrent disease including pancreatitis, infectious disease, urinary tract infection, neoplasia, and acromegaly as these conditions may increase the risk of developing ketoacidosis.

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

Cats considered to be at risk of developing diabetic ketoacidosis need close monitoring after initiation of treatment. The risk of developing diabetic ketoacidosis significantly decreases after the first two weeks of treatment, but DKA may occur at any time (see monitoring/precautions below).

Diabetic ketoacidosis (DKA) and ketonuria: Discontinue treatment immediately in the event of confirmed or suspected DKA or diabetic ketonuria and investigate accordingly. Due to the mode of action of SGLT-2 inhibitors, DKA may present *without* hyperglycaemia (known as euglycaemic DKA). A check for ketone bodies is therefore required prior to use and/ or whenever DKA is suspected; treatment with Senvelgo should not be initiated whilst urine ketone bodies are detected. Diagnosis of euglycaemic DKA can be based on the presence of ketone bodies and euglycaemia alongside clinical signs such as decreased appetite, acute vomiting, lethargy and dehydration. The presence of ketone bodies should prompt further

evaluation of the cat; in cases of clinical DKA, it is imperative to initiate treatment in accordance with standard DKA treatment protocols. This includes the prompt initiation of insulin therapy, administration of dextrose or other carbohydrate source as well as appropriate nutritional support. Checking for ketones is required at the initiation of therapy and every 1-3 days for the first two weeks, as well as whenever the cat is showing clinical signs of illness.

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

The safety and efficacy of the product has not been established in cats younger than 9 months and 4 years, respectively.

The safety and efficacy of the product has not been fully evaluated in severe cases of renal/liver/cardiac disease. Use only according to the benefit/risk assessment by the responsible veterinarian.

Remission

Remission of diabetes mellitus in cats is a complex phenomenon, which can be influenced by multiple factors in individual patients, such as glycaemic control, diet, age, weight, and/or genetics. Due to velagliflozin's mode of action it may be difficult to identify cats which are in remission, since they would not be expected to have hypoglycaemic events (unlike therapy with insulin). Consideration could be given to either continuing treatment with velagliflozin indefinitely or withdrawing treatment and closely monitoring glycaemic control and for return of clinical signs. If the patient relapses then velagliflozin treatment can be restarted.

Routine monitoring recommendations

Cats with diabetes mellitus and treated with the veterinary medicinal product should be routinely monitored according to standard DM treatment guidelines. In addition, due to the mode of action of velagliflozin, routine monitoring should include urinalysis (ketonuria, UTI), hydration status (osmotic diuresis) and body weight (unintended body weight loss due to persistent glucosuria).

Whenever clinical signs of DKA occur the cat should be evaluated for the presence of ketone bodies (e.g. ketonuria) indicating DKA or comorbidities causing insulin resistance. If the cat's clinical condition declines and/or blood glucose or fructosamine values worsen after initial improvement, additional diagnostics or alternative therapies may be required. Evaluation of haematology, serum chemistry, urinalysis and hydration status is recommended.

Due to their mode of action, SGLT-2 inhibitors may cause a mild increase in serum creatinine, BUN, phosphorus, and sodium within weeks of starting therapy, followed by a stabilisation of values. Routine evaluation of renal function, body weight and hydration status in patients with renal disease is recommended.

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

Accidental exposure to the product may cause increased urination, and symptoms of low blood pressure or low blood sugar, such as dizziness.
Take care to avoid children accessing an unattended filled syringe.
Do not leave the syringe unattended. Ensure that the food bowl is washed after the cat has eaten food which was mixed with the product.
If skin contact occurs, avoid hand-to-mouth contact, and wash hands immediately.
If symptoms occur, seek medical advice.

The product may cause slight irritation to the eyes.
Avoid contact with the eyes.
If contact with the eyes occurs, rinse immediately with water, and seek medical advice if symptoms persist.
The product includes propylene glycol, which may cause hypersensitivity reactions. People with known hypersensitivity to this substance should avoid contact with the product.

As no data are available to conclude that exposure to velagliflozin presents a risk to pregnant and/or breastfeeding women, they should consider wearing gloves in addition to standard hygiene practices.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use is not recommended during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Drug-drug interactions have not been investigated *in vivo*. The potential of drug-drug interactions is considered negligible as velagliflozin showed a low level of induction potential for liver microsomal cytochrome P450 (CYP450) enzymes in vitro. Concomitant treatment with diuretics has not been evaluated. Due to the pharmacodynamic effect, which may induce mild osmotic diuresis, concomitant treatment with diuretics may have a potential synergistic effect.

Overdose:
In a 90-day tolerance study evaluating repeated doses of 1 mg/kg, 3 mg/kg and 5 mg/kg velagliflozin in healthy cats, a dose dependent softening of stool was observed.

In a 180-day tolerance study evaluating repeated doses of 1 mg/kg, 3 mg/kg and 5 mg/kg of the product in healthy 9-month-old cats, the following were observed. Reduced weight gain was observed for both male and female cats receiving 5 mg/kg, and also in female cats receiving 1 mg/kg and 3 mg/kg of the product. Softer stools were observed in cats administered 5 mg/kg of the product. An increase of mean cholesterol values and a transient increase of mean triglyceride values were noted in cats administered 1 mg/kg, 3 mg/kg and 5 mg/kg of the product. Both remained within the respective reference range of historical controls in healthy animals and were of minor clinical relevance. Elevated reticulocyte counts, in excess of the normal reference range, were noted in cats administered 5 mg/kg of

the product, however this was not associated with any other haematological or clinical signs of anaemia. Elevations in serum calcium and magnesium levels were observed in cats administered 3 mg/kg and 5 mg/kg of the product, with magnesium values slightly exceeding the reference range. There were no associated clinical signs.

For animal treatment only.

## 7. ADVERSE EVENTS

| | |
|---|---|
| Very common (>1 animal / 10 animals treated): | Around half of cats can be expected to display loose stool/diarrhoea during treatment. In the majority of incidences loose stool/diarrhoea last for seven days or less and usually resolve without specific treatment. About 25% of cats can experience loose stool/diarrhoea lasting longer than 28 days. In case diarrhoea persists, alternative treatment for diabetes mellitus should be considered on a case by case basis.<br><br>Polydipsia / polyuria: resolves without additional treatment; may occur as part of the underlying disease or may be enhanced due to the osmotic effect of velagliflozin.<br><br>Weight loss: may occur as part of the underlying disease. An initial weight loss may occur due to the glucosuric effect of velagliflozin.<br><br>Mild dehydration |
| Common (1 to 10 animals / 100 animals treated): | Diabetic ketoacidosis (DKA): may be euglycaemic. Stop treatment and initiate insulin therapy. See also sections Contraindications and Special warning(s).<br><br>Diabetic ketonuria: stop treatment, undertake further investigations and manage accordingly (e.g. initiate insulin therapy). See also sections Contraindications and Special warning(s).<br><br>Urinary tract infection including cystitis caused by infection: may occur as part of the underlying disease. The glucosuric effect of velagliflozin may contribute to urinary tract infection. Standard cystitis/urinary tract infection therapy should be initiated.<br><br>Hypersalivation: usually at initial administrations only, occurs immediately following dosing and resolves quickly, without the need for treatment. |

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Velagliflozin inhibits the sodium-glucose co-transporter 2 (SGLT-2) which is predominantly expressed in the kidney. SGLT-2 is the primary transporter for the reabsorption of glucose from the urine. The inhibition of the SGLT-2 leads to glucose elimination in the urine and consequently results in a decrease in elevated blood

glucose levels in diabetic patients. This decrease is usually observed within 7 days after start of treatment.

The recommended dosing regimen is 1 mg/kg body weight once daily. The dosing regimen is the same regardless of prior treatment with insulin or another anti-diabetic medicinal product.
When transitioning from insulin, omit the insulin evening dose the day before starting velagliflozin treatment.

## 9. ADVICE ON CORRECT ADMINISTRATION

The solution should be drawn up using the dosing syringe provided in the package. The syringe fits onto the bottle and has a kg body weight scale, with 0.5 kg increments. The product may be administered either directly into the mouth or with a small amount of food, to ensure the entire dose is taken at once.

The medication should be given at approximately the same time every day.
If a dose is missed, it should be given as soon as possible on the same day.
After administration close bottle tightly with the cap. Do not wash the syringe with water.

## 10. WITHDRAWAL PERIOD(S)

Not applicable

## 11. SPECIAL STORAGE PRECAUTIONS

Shelf life after first opening the bottle: 6 months.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

## 12. SPECIAL PRECAUTIONS FOR DISPOSAL

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## 13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V
Veterinary medicinal product subject to prescription.

## 14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 08327/5004

Polyethylene bottle containing 30 ml with a polyethylene plug-in and a child resistant closure.
Each bottle is packed in a cardboard box equipped with a dosing syringe.

## 15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

[date]

## 16. CONTACT DETAILS

Marketing authorisation holder
Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

Manufacturer responsible for batch release:
Argenta Dundee Ltd
Kinnoull Road
Dunsinane Industrial Estate
Dundee
DD2 3XR
United Kingdom

## 17. OTHER INFORMATION

Approved 01 August 2023