SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Scovella 15 mg/ml oral solution for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Velagliflozin*	15 mg
*equivalent to velagliflozin L-proline H_2O	20.1 mg

Excipients:

Qualitative composition of excipients and other constituents
Ethanol
Propylene glycol
Citric acid monohydrate
Sodium hydroxide
Honey flavour
Water, purified

Clear, colourless to slightly yellow to slightly brown solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For the treatment of hyperinsulinaemia in insulin-dysregulated horses and ponies not responsive to changes in husbandry and exercise regimen.

3.3 Contraindications

Do not use in horses with anorexia.
Do not use in horses with hyperlipaemia and associated clinical signs such as inappetence or lethargy.

3.4 Special warnings

Laminitis is a common clinical sign of insulin dysregulation (ID).

Therefore, suitable endocrinologic tests should be conducted and clinical signs assessed to establish a diagnosis of insulin dysregulation (ID) prior to treatment. Insulin concentrations of horses may also be influenced by seasonal variation. The effect of velagliflozin treatment may vary depending on the husbandry practices employed, particularly in the context of a diet high in non-structural carbohydrates. Velagliflozin treatment cannot replace appropriate husbandry management of an ID horse, which includes dedicated diet and regular exercise, as feasible.

3.5 Special precautions for use

Special precautions for safe use in the target species:
In response to administration of velagliflozin and the resulting metabolic changes, an increase of triglycerides (TGs) in the blood (hypertriglyceridaemia) may occur. This hypertriglyceridaemia is usually asymptomatic and transient.

Triglyceride concentrations above reference ranges may be observed as part of the underlying metabolic profile in insulin-dysregulated horses. Measurement of triglyceride concentrations prior to initiation of treatment can provide a reference for the individual horse.

Triglyceride concentrations should be monitored following treatment initiation (e.g., after 4 to 14 days) as horses might develop transient hypertriglyceridaemia within the first weeks of treatment. In the event the increase of TGs is found to be clinically significant in an individual horse, appropriate follow-up monitoring is indicated.

In horses with hypertriglyceridaemia which do not show clinical signs of hyperlipaemia (such as inappetence or lethargy), the treatment can be continued based on a benefit-risk assessment by the attending veterinarian.

If significant hypertriglyceridaemia persists, continuation of treatment should be revisited based on a benefit-risk assessment by the attending veterinarian, also taking into account the potential presence of co-morbidities predisposing to increased TG concentration, e.g. hepatic lipidosis.

In case clinical signs of hyperlipaemia are observed, treatment should be paused until those signs are resolved. Treatment can be resumed as per assessment of the attending veterinarian.

If hypoglycaemia is suspected or confirmed, treatment should only be started after resolution.

Nutritional strategies for diet optimisation in line with guideline recommendations for management of ID should have been implemented prior to starting treatment with velagliflozin. The start of velagliflozin treatment should not coincide with abrupt feed restrictions in the context of dietary interventions or coincide with significantly reduced feed intake.

Due to the glucosuric effect of velagliflozin causing osmotic diuresis and potential volume depletion, constant free access to water for drinking must be ensured.

In clinical studies, velagliflozin at a dose of 0.3 mg/kg was given to 11 horses for 40 weeks. The safety and efficacy of the product has not been assessed for administration beyond this duration.

In pre-clinical and clinical studies, biochemical parameters, including insulin, returned to pre-treatment levels within 4 weeks following withdrawal of treatment. In one of these studies, without husbandry changes, elevated digital pulses were also observed in four out of six horses during the post-treatment period. One of these horses subsequently developed laminitis.

The duration and need for ongoing treatment should be determined on a case-by-case basis by the responsible veterinarian.

The safety and the efficacy of the veterinary medicinal product have not been investigated in horses under 3 years of age, nor in horses under 110 kg in bodyweight.

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. 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 contains 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 whether exposure to velagliflozin presents a risk to pregnant and/or breastfeeding women, they should consider wearing gloves in addition to standard hygiene practices.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses:

Very common (>1 animal / 10 animals treated):	Elevated triglyceride[1]
Common (1 to 10 animals / 100 animals treated):	Weight loss[2]
Undetermined frequency (cannot be estimated from available data)	Polyuria[3], polydipsia[4]

1 Severe hypertriglyceridaemia (> 5.7 mmol/L) is usually asymptomatic and transient (for monitoring recommendations see section ‘Special precautions for use’ above).

2 Weight loss may occur due to the glucosuric effect and the associated calorie loss and may be excessive. Undesirable weight loss can be mitigated by an appropriate diet plan in parallel to treatment.
3 Polyuria may occur due to the osmotic diuretic effect of velagliflozin-induced glucosuria.
4 Polydipsia may occur as compensation for polyuria (osmotic diuretic effect of velagliflozin-induced glucosuria).

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 its local representative 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

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation.
The use is not recommended during pregnancy or lactation.
Use only according to the benefit-risk assessment by the attending veterinarian.

Fertility:
The use is not recommended in breeding animals, as the safety of the veterinary medicinal product has not been established in the context of breeding.

3.8 Interaction with other medicinal products and other forms of interaction

Direct drug-drug interactions have not been investigated *in vivo*. The potential of drug-drug interactions is considered negligible for velagliflozin.

The concomitant use of pergolide and NSAIDs in horses receiving velagliflozin treatment has been investigated and did not impact the safety or efficacy of the veterinary medicinal product.

Limited data are available for concomitant use of metformin and levothyroxine in horses under velagliflozin treatment. The concomitant use of the veterinary medicinal product with other potentially blood insulin lowering pharmaceutical compounds has not been investigated.

Concomitant treatment with diuretics has not been evaluated. Due to the pharmacodynamic effect, which induces osmotic diuresis, concomitant treatment with diuretics may have a potential synergistic effect.

3.9 Administration routes and dosage

Oral use.

The recommended dose is 0.3 mg/kg bodyweight administered once daily.

The dosing syringe has a ml scale with 1 ml increments, corresponding to 1 ml per 50 kg bodyweight. For bodyweights in between dosing increments, rounding up to the next 1 ml increment is suggested.

Using the supplied dosing syringe, the product may be administered either directly into the mouth of the horse or added to a small amount of feed.

The first withdrawal should not exceed 10 ml, due to the vacuum present within the bottle.

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 the bottle tightly with the cap. Only the outside of the syringe should be rinsed with water and cleaned with a dry cloth. Keep the syringe assembled for effective use.

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

None observed at a once daily dose of 1 mg/kg bodyweight (corresponds to 3.3-fold the recommended dose) following administration for 16-weeks.

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 to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QA10BK90

4.2 Pharmacodynamics

Velagliflozin is a highly selective inhibitor of the sodium-glucose co-transporter 2 (SGLT-2), which is predominantly expressed in the kidney. Velagliflozin also has a minor inhibitory effect on the sodium-glucose co-transporter 1 (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 in the proximal tubules and 10% reabsorbed by SGLT-1. The inhibition of SGLT-2 leads to glucose elimination via the urine resulting in a rapid and sustained glucosuria. The resulting glucosuria leads to a modulation of glucose homeostasis, decreasing pancreatic

ß-cell sensitivity towards glucose and a reduction in pancreatic insulin secretion and circulating insulin concentrations.

A low level of glucose will continue to be resorbed due only to incomplete inhibition of SGLT-1, which prevents clinical hypoglycaemia.

The physiologic consequence of the glucosuric effect of SGLT-2 inhibitors is osmotic diuresis, which could lead to clinically apparent polyuria, and subsequentially to compensatory polydipsia.

In horses, a decrease in blood insulin concentrations may trigger lipolysis by reducing the inhibitory effect of insulin on the hormone-sensitive lipase. Depending on the nutrients available, horses have the ability to switch from a glucose-based, to a fatty acid-based, metabolism and utilise the released free fatty acids for energy. Unlike other species, they form ketone bodies at only a limited rate and instead convert unused free fatty acids into triglycerides.

4.3 Pharmacokinetics

Absorption:
An approximate dose-dependent increase of C_{max} and AUC of velagliflozin after dosing of 0.1 and 0.6 mg/kg was shown using the final formulation, with a calculated absolute bioavailability of about 30% and a T_{max} ranging between 1 to 4 hours. No obvious differences with regards to feeding status were observed.

Distribution:
In vitro equine plasma protein binding of velagliflozin was tested at 30, 300 and 3000 ng/ml and was 94.5%, 92.8% and 92.7% (mean: 93.3%), respectively.

The *in vitro* blood-to-plasma (B:P) partitioning of velagliflozin was tested at 3, 30, 300, and 3000 ng/ml in pooled equine blood and was 0.660, 0.728, 0.722 and 0.707 (mean 0.704), respectively.
After intravenous administration to horses, a mean volume of distribution (Vd) of 0.6 L/kg was determined, which indicates that velagliflozin does not partition out of systemic circulation.

Metabolism:
Comprehensive metabolite profiling of [^{14}C]-velagliflozin in equine liver microsomes and hepatocytes was performed. Low to moderate turnover in hepatocytes and liver microsomes was observed. Metabolites resulted from oxidation, and a combination of oxidation and dehydrogenation. Additionally, phase II metabolites resulting from direct glucuronidation, and combinations of oxidation and glucuronidation were detected in the hepatocyte incubations.

Elimination:
The mean terminal plasma half-life (T1/2) was independent of the dose and ranged between 7 and 8 h. Velagliflozin showed a low total clearance of 56 ml/h/kg.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 3 months.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

High-density polyethylene (HDPE) bottle containing 170 ml with a low-density polyethylene (LDPE) plug-in and a child resistant closure. Each bottle is packed in a cardboard box equipped with a 20 ml dosing syringe.

Cardboard box containing one bottle (1 x 170 ml) presentation.

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

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 61700/5047

8. DATE OF FIRST AUTHORISATION

01 April 2026

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

April 2026

LIMITED MARKETS:
Marketing authorisation granted for a limited market and therefore assessment based on customised requirements for documentation.

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: 07 May 2026