Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

**Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)**
**Federal Office of Consumer Protection and Food Safety**
**Gerichtstraße 49**
**13347 Berlin**
**(Germany)**

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

# Ursocalcin 240 mg/ml + 30 mg/ml solution for infusion

**Date: 29 October 2025**

# PRODUCT SUMMARY

| | |
|---|---|
| EU procedure number | DE/V/0352/001/DC |
| Name, strength and pharmaceutical form | Ursocalcin 240 mg/ml + 30 mg/ml solution for infusion |
| Applicant | Serumwerk Bernburg AG<br>Hallesche Landstrasse 105 B<br>06406 Bernburg (Saale)<br>Germany |
| Active substance(s) | Calcium gluconate monohydrate, Boric acid |
| ATC vetcode | QA12AA03 |
| Target species | Horses, cattle, sheep, goats, pigs |
| Indication for use | Cattle, sheep, goats: Parturient paresis (milk fever)<br>Mares: Lactation tetany<br>Sows: Eclampsia<br>Horses, cattle, sheep, goats, pigs: Supportive treatment of vascular permeability disorders, e.g. allergies and inflammation |

# PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

# SUMMARY OF ASSESSMENT

| | |
|---|---|
| Legal basis of original application* | Application in accordance with Article 18 of Regulation (EC) 2019/6 as amended. |
| Reference product (RP) | Calciumborogluconat-Infusionslösung |
| Marketing authorisation holder | Serumwerk Bernburg AG |
| Marketing authorisation number<br>EU procedure number | 3100133.00.00 |
| Date of authorisation | 23.06.2005 |
| Date of completion of the original decentralised procedure | 29 October 2025 |
| Concerned Member States for original procedure | ES, IT, PT |
| Concerned Member States for subsequent recognition procedure | n.a. |
| Withdrawn CMS during original decentralised procedure | n.a. |

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

## 1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the VMP can be assumed according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

## 2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

### A. Product description

The VMP contains 240 mg/ml calcium gluconate monohydrate and 30mg/ml boric acid as active substances and water for injections as excipient.

The container/closure system consists of 500 ml polypropylene infusion bottles with chlorobutyl rubber stoppers.

The choice of the absence of preservative are justified.

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

### B. Description of the manufacturing method

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

Process validation data on the VMP have been presented in accordance with the relevant European guidelines.

### C. Production and control of starting materials

The active substances are calcium gluconate monohydrate and boric acid, two established active substances described in the European Pharmacopeia. The active substances are manufactured in accordance with the principles of good manufacturing practice.

The active substance specifications are considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with these specifications have been provided.

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

### D. Control tests carried out on isolated intermediates during the manufacturing process

Not applicable.

### 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 VMP.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

### F. Stability tests

Stability data on the active substances have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substances when stored under the approved conditions.

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

### G. Other information

Not applicable.

## 3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, results of toxicological or residue studies are not required.

Warnings and precautions as listed in the product literature are the same as those of the reference VMP and supplemented with additional statements, based on increased knowledge and the current state of science.

The product information is considered adequate to ensure safety of the product for users, the environment and consumers.

### A. Safety tests

#### *Pharmacological studies*

As this is a generic application submitted according to Article 18 of Regulation (EC) No 2019/6, documentation is not required.

#### *Toxicological studies*

As this is a generic application submitted according to Article 18 of Regulation (EC) No 2019/6, documentation on toxicity is not required.

#### *User safety*

The applicant has provided a user safety assessment in compliance with the current CVMP guidance, “Guideline on user safety for pharmaceutical veterinary medicinal products” (EMA/CVMP/543/03-Rev.1), which shows that there is a risk of skin / eye irritation as well as a risk of local effects at the injection site due to accidental self-injection.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

### *Environmental Risk Assessment*

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

**Phase I:**

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the active substance is a natural substance, the use of which will not alter the concentration or distribution of the substance in the environment.

## *B. Residues documentation*

### *Residue tests*

No residue depletion studies were conducted on the basis that the reference product was described as essentially similar in terms of qualitative and quantitative composition of active substances and of the excipient. Since this is accepted (in line with the current CVMP 'Guideline on the conduct of bioequivalence studies for veterinary medicinal products' (EMA/CVMP/016/2000-Rev.4)), and the administration routes, dosages and target animal species are also the same as for the reference product, the justification for the absence of residue data is considered valid.

### *Maximum Residue Limits*

The active substances calcium gluconate monohydrate and boric acid are included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

| **Pharmaco-logically active substance** | **Marker residue** | **Animal Species** | **MRL** | **Target tissues** | **Other provision** | **Therapeutic Classifi-cation** |
|---|---|---|---|---|---|---|
| Calcium gluconate | NOT APPLICABLE | All food producing species | No MRL required | NOT APPLICABLE | NO ENTRY | NO ENTRY |
| Boric acid and borates | NOT APPLICABLE | All food producing species | No MRL required | NOT APPLICABLE | NO ENTRY | NO ENTRY |

The sole excipient water for injections is considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009–Rev.57; status "no MRL evaluation required", entry 'Aqua purificata').

***Withdrawal Periods***

Based on the data provided above, Zero-day withdrawal periods for meat and offal as well as for milk of the target species are justified. The withdrawal period texts of the reference product were slightly amended to express the milk withdrawal periods in hours:

Cattle, sheep, goats, horses:

Meat and offal: Zero days.
Milk: Zero hours.

Pigs:
Meat and offal: Zero days.

## 4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been justified, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

## 5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the VMP for humans and the environment is acceptable.

## POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

This section contains information on significant changes, which have been made after the original procedure, which are important for the quality, safety or efficacy of the VMP.

None.