**Institute for State Control of Veterinary Biologicals and Medicines**
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**Reference Member State: CZ**

**DECENTRALISED PROCEDURE**

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

# BelaZin 20 mg/ml solution for injection for cattle, horses, dogs and cats (AT, BG, CY, CZ, EE, EL, FR, HR, HU, LT, LU, LV, NL, PT, RO, SI)
# Xalyzin 20 mg/ml solution for injection for cattle, horses, dogs and cats (DE)

# MODULE 1

## PRODUCT SUMMARY

| | |
|---|---|
| EU Procedure number | CZ/V/0159/001/DC |
| Name, strength and pharmaceutical form | BelaZin 20 mg/ml solution for injection for cattle, horses, dogs and cats (AT, BG, CY, CZ, EE, EL, FR, HR, HU, LT, LU, LV, NL, PT, RO, SI)<br>Xalyzin 20 mg/ml solution for injection for cattle, horses, dogs and cats (DE) |
| Applicant | bela-pharm GmbH Co.KG<br>Lohner Strasse 19<br>Vechta 49337<br>Germany |
| Active substance(s) | XYLAZINE HYDROCHLORIDE |
| ATC Vet Code | QN05CM92 |
| Target species | Cattle, horses, dogs and cats |
| Indication for use | Horses:<br>For sedation and muscle relaxation. In combination with other substances for analgesia and anaesthesia.<br>Cattle:<br>For sedation, analgesia and muscle relaxation. In combination with other substances for anaesthesia.<br>Dogs, cats:<br>For sedation. In combination with other substances for analgesia, anaesthesia and muscle relaxation. |

# MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

# MODULE 3

## PUBLIC ASSESSMENT REPORT

| | |
|---|---|
| Legal basis of original application | Generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended |
| Date of completion of the original decentralised procedure | 05/02/2020 |
| Date product first authorised in the Reference Member State (MRP only) | Not applicable |
| Concerned Member States for original procedure | AT-BG-CY-DE-EE-EL-FR-HR-HU-LT-LU-LV-NL-PT-RO-SI |

## I. SCIENTIFIC OVERVIEW

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; the adverse reactions observed are indicated in the SPC.
The product 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 product was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

## II. QUALITY ASPECTS

### *A. Qualitative and quantitative particulars*

The product contains 20.0 mg of xylazine per 1 ml (which is equivalent to 23.3 mg of xylazine hydrochloride per 1 ml) and the excipients methyl parahydroxybenzoate and water for injections.

The container/closure system consists of 25ml clear type I glass vials and 50ml clear type II glass vials. The vials are closed with bromobutyl rubber stoppers and aluminium caps.

The choice of the formulation is justified.

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

### *B. Method of Preparation of the Product*

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

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

### *C. Control of Starting Materials*

The active substance is xylazine hydrochloride, 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.

Scientific data and certificates of suitability issued by the EDQM have been provided.

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

### *D. Control on intermediate products*

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 product.

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*

Stability data on the active substance are covered by the relevant certificates of suitability issued by the EDQM.

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

The in-use shelf-life of the product is supported by relevant data.

## III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, and the exemption from bioequivalence is claimed on the basis of the product being identical to the reference product, results of the safety tests are not required.

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

## III.A Safety Testing

### User Safety

The applicant has provided a user safety assessment 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.

### Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.
The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will be used to treat a small number of animals in a flock or herd.

The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

## III.B Residues documentation

This is a generic application according to article 13 (1) of Directive 2001/82/EC, as amended. The generic product has the same pharmaceutical form as the reference product and the formulation of the generic product is essentially similar to formulation of the reference product 'Xylasol 20 mg/ml'.

### Residue Studies

No residue depletion studies were conducted.

### MRLs

The active substance xylazine hydrochloride is allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs (µg/kg) | Target tissues | Other provisions |
|---|---|---|---|---|---|
| Xylazine hydrochloride | NOT APPLICABLE | Bovine, *Equidae* | No MRL required | NOT APPLICABLE | NO ENTRY |

Both excipients are included in view of MRL.

### Withdrawal Periods

Based on the data provided above the following withdrawal periods are established:

Withdrawal period(s):
*Cattle:*

Meat and offal: 1 day
Milk: zero hours

*Horses:*
Meat and offal: 1 day
Not authorised for use in mares producing milk for human consumption.

## IV. CLINICAL ASSESSMENT (EFFICACY)

This is a generic application according to article 13 (1) of Directive 2001/82/EC, as amended by Directive 2004/28/EC. The product has the same pharmaceutical form as the reference product, the same qualitative and quantitative composition of active substance and excipients. The efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product Xylosol 20 mg/ml - Injektionslösung für Tiere.

## 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 risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

# MODULE 4

## POST- AUTHORISATION ASSESSMENTS

**Not applicable.**