Austrian
Federal Office for
Safety in Healthcare
BASG

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Xylamidor 20 mg/ml solution for injection for cattle, horses, dogs and cats

Date: 06/07/2023

PRODUCT SUMMARY

EU procedure number	AT/V/0029/001/DC
Name, strength and pharmaceutical form	Xylamidor 20 mg/ml solution for injection for cattle, horses, dogs and cats
Applicant	Richter Pharma AG Feldgasse 19 4600 Wels Austria
Active substance(s)	XYLAZINE HYDROCHLORIDE
ATC vetcode	QN05CM92
Target species	Cattle, horses, dogs, cats
Indication for use	Cattle For sedation, muscle relaxation and analgesia for minor surgery. In combination with other substances for anaesthesia. Horses For sedation and muscle relaxation. In combination with other substances for analgesia and anaesthesia. Dogs, cats For sedation. In combination with other substances for analgesia, anaesthesia and muscle relaxation.

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	Generic application in accordance with Article 18 of Regulation (EC) 2019/6 as amended. Reference veterinary medicinal product: Rompun 20 mg/ml solution for injection
Date of completion of the original decentralised procedure	03/05/2023
Date of the veterinary medicinal product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	Belgium, Slovakia, Cyprus, Germany, Denmark, Greece, Spain, Finland, France, Ireland, Italy, Latvia, Netherlands, Norway, Poland, Romania, Sweden, Slovenia, Bulgaria
Concerned Member States for subsequent recognition procedure	n.a.
Withdrawn CMS during original decentralised procedure	None.

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 and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the VMP was demonstrated 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 XYLAZINE HYDROCHLORIDE (equivalent to 20 mg Xylazine) and the excipients Methyl parahydroxybenzoate (E218) and Sodium chloride.

Container/closure system: Clear glass vial type I with 10 ml solution for injection or clear glass vial type II with 25 ml or 50 ml solution for injection, closed with a coated bromobutyl rubber stopper, type I and aluminium cap.

The choice of the formulation and presence 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 licensed manufacturing sites.

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 substance is XYLAZINE HYDROCHLORIDE, an established active substance described in the European Pharmacopeia. 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.

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

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 sites have been provided demonstrating compliance with the specification.

F. Stability tests

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance 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.

3. SAFETY DOCUMENTATION (safety and residues tests)

This is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with the reference VMP has been demonstrated.

A. Safety tests

Pharmacological studies

Xylazine acts as an agonist of the α_2-adrenergic receptor on the presynaptic and postsynaptic receptors of the central and peripheral nervous system.

Xylazine is quickly absorbed and distributed in the animal.

Due to the legal base of the application, the applicant is not required to submit pharmacological data. The applicant has not submitted these data on the basis that essential similarity with the respective reference product has been demonstrated.

Toxicological studies

Due to the legal base of the application, the applicant is not required to submit toxicological data. The applicant has not submitted these data on the basis that essential similarity with the respective reference product has been demonstrated.

Observations in humans

Since xylazine is not used in human medicine, information on its effects in humans is limited. Accidental exposure of humans to xylazine may result in depression of the central nervous system, hypotension, bradycardia, respiratory depression, miosis, hyperglycaemia, and hypothermia (Forrester, 2016).

Development of resistance and related risk in humans

Not applicable.

User safety

Since the application was submitted in accordance with Article 18 of Regulation (EU) 2019/6 as amended, for a generic veterinary product, the same warnings and precautions as approved for the reference product were established.
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 for all target species and no Phase II assessment is required.

Based on the data provided, it is endorsed that the use of the product applied for is unlikely to represent an unacceptable risk to the environment when used according to the instructions for use as outlined in the product information.

B. Residues documentation

Maximum Residue Limits

Xlazine is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

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

Withdrawal Periods

Since the application was submitted in accordance with Article 18 of Regulation (EU) 2019/6 as amended, for a generic veterinary product, the same withdrawal periods as approved for the reference product were established:

Cattle, horse:
Meat and offal: 1 day
Milk: zero hours.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to the reference VMP has been demonstrated, 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.

Sequence of significant variations

Summary of change (Application number)	Approval date
<None> (AT/V/0029/001…)	