DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Geslin 0.0040 mg/ml injectable solution for cattle, horse, pig and rabbit

CORREO ELECTRÓNICO

mresvet@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 54 01
FAX: 91 822 5443

PRODUCT SUMMARY

EU procedure number	ES/V/0434/001/MR
Name, strength and pharmaceutical form	Geslin 0.0040 mg/ml solution for injection for cattle, horse, pig and rabbit
Applicant	Mevet S.A.U. Avinguda Industria 409-410 Poligono Industrial El Segre 25191 Lleida Spain
Active substance(s)	Buserelin
ATC vetcode	QH01CA90
Target species	Cattle (cow), horse (mare), pig (sow for reproduction) and rabbit (female for reproduction)
Indication for use	Cattle (cow): - Treatment of follicular cysts. - Anoestrus due to acyclia (not due to the presence of corpus luteum). - Improvement of conception rate in females with a history of delayed ovulation. - Follicular atresia. - Improving the conception rate in artificial insemination or mating. Horse (mare): - Treatment of follicular cysts. - Anovulation associated with prolonged oestrus despite the presence of a mature follicle. - Ovulation induction. Pig (sow for reproduction): - Ovulation induction. Rabbit (female for reproduction): - Ovulation induction postpartum. - Improving the conception rate in insemination or mating.

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 (EU) 2019/6 as amended.
Reference product (RP)	RECEPTAL Solución inyectable
Marketing authorisation holder	Merck, Sharpe and Dohme Animal Health, S.L.
MS where the RP is or has been authorised	Spain
Marketing authorisation number	1106 ESP
EU procedure number	-
Date of authorisation	24-06-1996
Date of completion of the original mutual recognition procedure	Day 90: 20/12/2023
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	11/07/2017
Concerned Member States for original procedure	CY, EE, PL, RO
Withdrawn CMS during original mutual recognition procedure	-

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 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)

2.A. Product description

The VMP contains 0.0040 mg/ml of buserelin acetate and the excipients benzyl alcohol, sodium chloride, sodium dihydrogen phosphate monohydrate, sodium hydroxide, hydrochloric acid and water for injections.

The container/closure system is a type I colourless glass vial of 20 ml fill volume, closed with bromobutyl rubber stopper and sealed with aluminium cap.

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

2.B. Description of the manufacturing method

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

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

2.C. Production and control of starting materials

The active substance is buserelin, an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practices.

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.

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

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

2.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.

2.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 product throughout its shelf life when stored under the approved conditions.

2.G. Other information

N/A

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of pharmacological and toxicological tests are not required.

The safety aspects of this VMP are identical to the reference VMP.

Warnings and precautions as listed on the product literature are the same as those of the reference VMP and are adequate to ensure safety of the product to users, the environment and the consumers.

3.A. Safety tests

User safety

The applicant has provided a user safety assessment, which confirms that the risk for the user is the same as that of the reference product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP. A warning regarding the possible allergic reactions caused by the excipient benzylalcohol has been added.

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 initial predicted environmental concentration in soil is less than 100 µg/kg.

PECsoil Dairy cow = 0.0002 µg/kg soil
PECsoil Cattle (>2 years) = 0.0003 µg/kg soil
PECsoil Sow (with litter) = 0.0001 µg/kg soil
PECsoil Horse = 0.0005 µg/kg soil
PECsoil Rabbit = 0.0043 µg/kg soil

No unacceptable risks for the environment are expected when the product is handled, used and disposed according to the information included in the SPC and PL.

3.B. Residues documentation

Residue tests

No residue depletion studies were conducted because bioequivalence between the candidate and a reference product has been demonstrated. The same withdrawal periods approved for the reference product are applicable to the generic.

Maximum Residue Limits

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

Pharmacologically active substance	Marker residue	Animal Species	MRL	Target tissues	Other provision	Therapeutic Classification
Buserelin	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY

Withdrawal Periods

Based on the data provided above, a withdrawal period of zero days for meat in cattle (cow), horse (mare), pig (sow for reproduction) and rabbit (female for reproduction), and zero days for milk in cattle (cow) and horse (mare) are justified.

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 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.

None.