Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A PROPOSED VETERINARY MEDICINAL PRODUCT

Procaine and Adrenaline Injection Procaine Hydrochloride 40 mg/ml, Adrenaline Tartrate 0,036 mg/ml, Solution for Injection

NOTE: This medicine was refused authorisation

Date Created: March 2025

MODULE 1

PROPOSED PRODUCT SUMMARY

Name, strength and pharmaceutical form	Procaine and Adrenaline Injection Procaine Hydrochloride 40 mg/ml, Adrenaline Tartrate 0,036 mg/ml, Solution for Injection
Applicant	Forte Healthcare Licencing Ltd Cougar Lane, Naul Hazardstown Co. Dublin, K32 TE86 Ireland
Active substances	Procaine hydrochloride Adrenaline tartrate
ATC Vetcode	QN01BA52
Target species	Horses, cattle, pigs and sheep
Indication for use	Local anaesthetic

MODULE 2

As the product was refused a marketing authorisation, a Summary of Product Characteristics was not approved for this product.

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Bibliographic application in accordance with: - Schedule 1, Paragraph 7 of the Veterinary Medicines Regulations 2013, as amended for GB, and - Article 22 of Regulation (EC) 2019/6 for NI
Date of conclusion of the procedure	10/02/2025

SCIENTIFIC OVERVIEW

The application was for a Marketing Authorisation in GB and NI, and was assessed in accordance with Schedule 1, Paragraph 7 of the Veterinary Medicines Regulations 2013 (as amended) for GB and in accordance with Article 22 of Regulation (EC) 2019/6 for NI.

In light of the overall data submitted and the scientific discussion within the VMD, a negative opinion for Procaine and Adrenaline Injection was adopted. The overall benefit/risk analysis was not in favour of granting a marketing authorisation.

PROPOSED INDICATION

Procaine and Adrenaline Injection Procaine Hydrochloride 40 mg/ml, Adrenaline Tartrate 0,036 mg/ml, Solution for Injection was expected to be used for local anaesthesia where a long-term anaesthetic effect is desired (1-2 hours). It was intended for subcutaneous or perineural use in horses, cattle, pigs and sheep.

METHOD OF ACTION

Procaine is a benzoic acid derivative with local anaesthetic properties. It binds to the receptors of the voltage-gated sodium channels on neurons, preventing sodium influx, thereby inhibiting depolarisation needed for nerve impulse conduction and producing an analgesic effect.

Adrenaline is a sympathomimetic catecholamine that binds non-selectively to alpha and beta-adrenergic receptors. When adrenaline is combined with a local anaesthetic, it prolongs the anaesthetic effect. Adrenaline causes local vasoconstriction, which reduces blood flow and therefore decreases the uptake of local anaesthetic into the circulation, therefore, reducing the plasma concentration

of the local anaesthetic and thus decreases its potential toxicity. It also produces a more reliable block, which intensifies anaesthesia and analgesia.

REASONS FOR REFUSAL

At the time of the initial assessment there were a number of deficiencies in the dossier.

Chemical, Pharmaceutical & Biological Documentation
The stability data suggested that, based on the proposed formulation, only a limited shelf life would be possible which would not be commercially viable.

Safety & Residues Documentation
The user safety assessment could not be appropriately assessed based on the number of insufficiencies in the data. There were insufficient data on pharmacokinetic properties of both active substances in the target species and there was no information pertaining to the depletion residues of either active substance from the injection site.

Pre-Clinical & Clinical Documentation
There was no pharmacodynamic data pertaining to horses, sheep, cows, or pigs and pharmacokinetic data for horses only. No new dose determination or confirmation studies had been conducted with the candidate product, nor any published literature to justify the well-established use of the proposed dosing regimen for infiltration and perineural local anaesthesia in the target species. No new proprietary studies regarding target species tolerance were provided and insufficient bibliographic evidence to support tolerance in all four target species. Insufficient bibliographic evidence has been provided to support the inclusion of pigs, sheep, cows, or horses as target species for the indications listed.

OVERALL CONCLUSION AND BENEFIT–RISK ASSESSMENT

Whilst the concerns might have been resolvable, it was considered that it was not appropriate for the applicant to address these significant deficiencies within the timeframe of the application process. In conclusion, the data submitted in the dossier do not support a favourable benefit/risk profile for the product, and the application has been refused.

The grounds for refusal were as follows:

- With respect to Great Britain, as per the UK Veterinary Medicines Regulations 2013 (as amended), the Secretary of State must refuse to grant a marketing authorisation if the data submitted with the application are inadequate (Schedule 1, Part 3, paragraph 24.2a).

- With respect to Northern Ireland, criteria 2a) and 2c) of Article 37 (Decisions refusing marketing authorisations) are considered applicable,

i.e. 'the application does not comply with this Chapter' and 'the applicant has not provided sufficient information on the quality, safety or efficacy of the veterinary medicinal product'.

MODULE 4

POST- AUTHORISATION ASSESSMENTS

As the application was refused, there are no post-authorisation assessments.