IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Hornex 42.7% w/w Cutaneous paste

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Hornex 42.7% w/w Cutaneous paste
Active substance	Sodium hydroxide
Applicant	Agri-Lloyd Limited Unti 1 Millennium Business Park Finglas Dublin Ireland
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC, as amended.
Date of authorisation<AUTHORISATION procedure of completion>	
Target species	Cattle
Indication for use	For the removal of embryo horns on calves not older than 7 days old
ATCvet code	QD11AX

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

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 slight reactions observed are indicated in the SPC.

The product is safe for the user, the consumer and 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 benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The product contains 42.7 % w/w sodium hydroxide and the excipients acetylsalicyclic acid, arachis oil and water.
The product is packaged in a 39 ml polypropylene securitainer with tamper evident polyethylene lid, containing either 25g or 40g.

The product is applied to the horn buds using a flat wooden spatula, 90 mm x 7 mm.

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 for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is sodium hydroxide is an atypical active substance. The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification has been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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

F. Stability

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

G. Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13(1) of the Directive (as amended) and bioequivalence with the authorised reference product Hornex 42.7 w/w Cutaneous Paste (Vm 36237/4000, Gibraltar UK Ltd) is accepted (on the basis that the products are identical in terms of composition), results of safety and residues tests are not required.

The safety and efficacy aspects of this product are identical to the reference product.

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

III.A Safety Testing

User Safety

It is accepted that the user safety profile will be 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 product.

Environmental Risk Assessment

Given the nature of this product and the proposed conditions of use, it is accepted that this product does not pose a risk to the environment.

III.B Residues Documentation

Residue Studies

No residue depletion studies were conducted.

MRLs

The active ingredient, sodium hydroxide (E524) is listed in Table I of the Annex to Commission Regulation (EU) No 37/2010 as follows:

	Bovine
Muscle	Not applicable
Liver	Not applicable
Kidney	Not applicable
Fat/ skin	Not applicable
Milk	Not applicable

Withdrawal Periods

Based on the data provided above, a withdrawal period of zero hours for meat in cattle is justified, in line with the reference product.

IV. CLINICAL ASSESSMENT

As this is a generic application according to Article 13(1) of the Directive (as amended) and bioequivalence with the authorised reference product Hornex 42.7 w/w Cutaneous Paste (Vm 36237/4000, Gibraltar UK Ltd) is accepted (on the basis that the products are identical in terms of composition), results of efficacy tests are not required. The efficacy claims for this product are the same as those of the reference product.

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

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

VI. POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the HPRA website.

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 product.

Changes:
None.