Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Hornex 42.7% w/w Cutaneous paste

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition	Quantitative composition
Active substance:	
Sodium hydroxide	42.7% w/w

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous paste. A pale pink to white buttery textured paste.

4 CLINICAL PARTICULARS

4.1 Target Species

Calves not more than 7 days old.

4.2 Indications for use, specifying the target species

For the removal of embryo horns on calves not older than 7 days old.

4.3 Contraindications

Do not allow paste to become wet following application. Do not apply to calves over 7 days old.

4.4 Special warnings for each target species

Do not use on calves over 7 days old. Keep cow away from calf for ½ hour. For external use only.

4.5 Special precautions for use

i. Special precautions for use in animals.
Smear petroleum jelly around the bud before application. The operator should wear protective gloves to apply the paste. Allow 1 ½ hours of dry weather when applying paste. Keep paste away from animal's eyes. Keep cow away from calf for half an hour after application of paste.

ii. Special precautions for the person administering the veterinary medicinal product to animals.
Caustic. Personal protection equipment should be worn to prevent contact with skin – wear household rubber gloves, heavy-duty overalls and eye/face protection when applying the product. In the event of eye contact – immediately irrigate with plenty of clean water. Seek medical attention immediately.
In the event of skin contact – remove contaminated clothing, taking care not to further contaminate the affected area, wash with copious amounts of water.
Ingestion – while confined to mouth, give large quantities of water as mouthwash, ensure mouthwash is not swallowed. If swallowed, give copious amounts of water or milk. Do not induce vomiting.
In case of accidental ingestion or spillage onto skin, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

If paste should enter calves' eye(s), flush liberally with clean water and seek veterinary attention.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Remove the hair around the embryo horn by cutting. Smear petroleum jelly around the bud, then apply paste to cover the entire horn bud, using the enclosed applicator. Dose per embryo horn is approximately 0.22 g paste, and is the size of a small pea. One application is usually sufficient. Do not allow paste to become wet following application.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

As the dose is not specific, any excess of paste applied should be removed with a damp cloth.

4.11 Withdrawal period(s)

Meat – zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dermatological

ATC Vet Code: QD11AX

5.1 Pharmacodynamic properties

Caustic action, causing breakdown of horn tissue to ensure removal of the horn buds.

5.2 Pharmacokinetic particulars

The product acts topically resulting in the destruction of tissue to which it is applied.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetylsalicyclic acid
Arachis Oil
Water

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25 °C.
Do not freeze.
Protect from direct sunlight.
Replace cap tightly after use.

6.5 Nature and composition of immediate packaging

Aqueous paste contained in 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Agri-Lloyd Limited
Unit 1
Millennium Business Park
Finglas
Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22762/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 October 2016

10 DATE OF REVISION OF THE TEXT

April 2019