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.

4.6 Adverse reactions (frequency and seriousness)
If paste should enter calves' eye(s), flush liberally with clean water.

4.7 Use during pregnancy, lactation or lay
Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction
None known.

4.9 Amount(s) 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
Meat – zero days.

5. PHARMACOLOGICAL 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 properties
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 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 ºC.
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 of Hornex.

Hornex 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 product or waste materials derived from the use of such products, if appropriate

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

Gibraltar (UK) Ltd
Animal House
Boundary Road
Lytham
Lancashire
FY8 5LT

8. MARKETING AUTHORISATION NUMBER

Vm 36237/4000

9. DATE OF FIRST AUTHORISATION

Date: 8th December 1993

10. DATE OF REVISION OF THE TEXT

Date: August 2014

20 August 2014