

IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10206/008/001**
Case No: 7002970

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

Ovelle Ltd

Industrial Estate, Coe's Road, Dundalk, Co. Louth

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Hornoff

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Hornoff

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Potassium Hydroxide 81 % w/w

3 PHARMACEUTICAL FORM

Cutaneous stick.

4 CLINICAL PARTICULARS

4.1 Target Species

Bovine.

4.2 Indications for use, specifying the target species

De-horning of young calves between 2-14 days old.

4.3 Contraindications

Do not use in calves with well developed horns.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Do not handle the product. Wear rubber gloves. After use wash gloves and hands. If Hornoff comes in contact with skin or clothes, wash with water. In case of ingestion, copious amounts of water, vinegar or citric acid should be given, followed by demulcent drinks and olive oil. Milk is also helpful. Avoid vomiting.

4.6 Adverse reactions (frequency and seriousness)

Burning of skin around horn bud due to incorrect use.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

Not applicable

4.9 Amounts to be administered and administration route

When the calf is 2 to 14 days old horns buds can be felt. Clip hair around the small horn buds, cover shaven area with Vaseline. Then moisten the tip of the horn bud with a drop of water, rub Hornoff stick on tip of bud, avoiding the surrounding skin. A slight scratch on tip of bud increases effectiveness. One or two applications should be sufficient.

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

If bleeding occurs the application should be discontinued immediately. Apply a pad with dilute vinegar to neutralise the caustic action.

4.11 Withdrawal Period(s)

Meat: zero days

Milk: not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Potassium Hydroxide is a corrosive caustic, which destroys tissue when in contact – this action is used to destroy the horn-buds in young calves. If absorbed Potassium Hydroxide is totally ionised, and the potassium ions would be assimilated.

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

6.2 Incompatibilities

None known.

6.3 Shelf-life

2 years.

6.4 Special precautions for storage

Do not store above 25oC.

6.5 Nature and composition of immediate packaging

30ml sterlin container with polyethylene screw caps (Sterlin is a special mixture of polystyrene/polyethylene). A polythene bag 15.5cms x 10cms. Each container contains 1 stick (14g approx).

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

If Hornoff liquefies, dispose of safely by washing down the drain with plenty of cold water.

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Ovelle Limited,
Industrial Estate,
Coe's Road,

<?xml:namespace prefix = st1 ns = "urn:schemas-microsoft-com:office:smarts" /><st1:place w:st="on">Dundalk</st1:place>,
<st1:place w:st="on">Co.</st1:place> Louth.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10206/8/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2001

10 DATE OF REVISION OF THE TEXT