IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10944/005/001**
Case No: 7001808

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

PharVet Ltd

Station Road, **Bagenalstown**, **Co. Carlow**, **Ireland**

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:

Cheno Unction 0.05%

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.

The authorisation, unless previously revoked, shall continue in force from **01/10/2006**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Cheno Unction 0.05%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance
Cypermethrin cis:trans 50:50 0.05% w/w

Excipients
Chlorophyll Dye (E140) 0.04% w/w
Phenol 80% Liquid 1 % w/w

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Ointment.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Cheno Unction 0.05% is a barrier ointment and is recommended for use in cattle as an aid in the treatment of skin lesions (such as cuts, sores, grazes, bruises and minor skin abrasions), common particularly on cow's teats. It has fly repellent properties and is also useful for protection against harsh weather conditions.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

Teats should be well washed and dried before milking, preferably with an individual paper towel.

4.5 Special precautions for use

Special precautions for use in animals

When used on teats and udders of lactating dairy cows, teats should be well washed and dried before milking preferably with an individual paper towel.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after use.
Gloves should be worn while applying the product.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

This product may be used in pregnant and lactating cattle.

4.8 Interaction with other medicinal products and other forms of interaction

There are no known interactions with other medicaments. Cheno Unction 0.05% will react long-term with rubber liners of milking machines if Cheno Unction 0.05% is improperly used.

4.9 Amounts to be administered and administration route

For topical use only.
There is no recommended standard dose as the amount of Cheno Unction 0.05% to be applied to the animal will largely depend on the area requiring to be covered e.g. 2g per teat and 8-10g/udder and teats. The wound should be clean and covered with a small amount of Cheno Unction 0.05%. Repeat as is necessary. As a barrier treatment against weather conditions the recommendations are ‘apply a thin coating of Cheno Unction 0.05% and rub in well’.

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

Not applicable.

4.11 Withdrawal Period(s)

Meat: Nil.
Milk: Nil.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Cheno Unction 0.05% is a barrier ointment with insect repellency. The formulation, which consists of a mixture of wax, petroleum jelly, colophony resin and liquid paraffin, is unlikely to release the active for absorption by the skin.

Cypermethrin is an insecticide with good 'knock – down' and repellency action. When applied topically to humans as a spray, the absorption rate was 3% of the total dermal dose. No toxic or adverse effects were observed. In a barrier ointment with characteristics to prevent absorption, it is reasonable to expect a lower absorption rate. Over 90% of oral intake is excreted in 96 hours. Elimination occurs via the urine and 20% through the faeces as the unchanged molecule.

Research has shown that milk and serum taken from cows treated twice daily with Cheno Unction 0.05% for 5 days showed no traces of Cypermethrin or phenol.

Treated animals showed no signs or irritancy and milk yield from treated animals showed a similar pattern to untreated cows in a blind trial basis.

Colophony Resin BP is included in the formulation as an excipient to provide an acceptable base. It is used primarily to improve adhesiveness of the ointment, but it may also have some antiseptic and astringent properties.

Phenol may have some pharmacological effect, as it is a potent bacteriostat with antiseptic characteristics at lower concentrations. It is also antipruritic. Phenol is soluble in oils and in this preparation, this attribute minimises skin penetration.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Yellow Soft Paraffin
Hard Paraffin
Liquid Paraffin
Colophony
Phenol
Chlorophyll dye (E140)

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^{o}C.

6.5 Nature and composition of immediate packaging

230g, 450g and 1kg tins are made of tin plate. The 230g and 450g are lever lid containers with safety rings included. The 2.25kg packs are polyethylene co-polymer and the lid is L.D.P.E.

Not all pack sizes may be marketed.

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

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

PharVet Ltd.
Station Road
Bagenalstown
Co. Carlow
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10944/5/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2006

10 DATE OF REVISION OF THE TEXT

4th May 2006