IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10834/002/001**
Case No: 7001329

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:

Animax

Shepherds Grove West, **Stanton**, **Suffolk IP31 2AR**, **United Kingdom**

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:

Copinox 27g Capsules

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 **01/08/2006**.

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

Copinox 27g Capsules.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 27g capsule contains:	
Active Substance	
Copper oxide	27.00 g
(equivalent to elemental copper	23.49 g)
Excipient	
Gelatin capsule	

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard.
Maroon coloured hard gelatin capsules containing grey particles of needle form shape.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

For the long-term control of copper deficiency in cattle.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Animals should only be dosed with Copinox capsules if they are known to be suffering from or at risk from copper deficiency.

4.5 Special precautions for use

Special precautions for use in animals

Care must be taken when dosing animals to avoid causing injury to the mouth and pharynx. No other form of copper supplementation should be given prior to, or for six months after administration of Copinox capsules.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Not to be expected provided the recommended dosage regime is followed.

4.7 Use during pregnancy, lactation or lay

No adverse effects known.

4.8 Interaction with other medicinal products and other forms of interaction

Copper interacts with many other elements most important of these is molybdenum. This interaction may lead to the formation of insoluble copper molybates which may reduce the absorption of copper and molybdenum from the gut.

4.9 Amounts to be administered and administration route

The capsule should be administered orally over the back of the tongue.

Young stock (100 – 250 kg bw): one 27 g (maroon) capsule.
Cattle (over 250 kg bw): one or two x 27 g (maroon) capsules.

The recommended dose should maintain adequate copper levels for the whole of the grazing season unless more frequent dosing is recommended on veterinary advice.

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

None known.

4.11 Withdrawal Period(s)

Meat/Milk: Nil.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Alimentary tract and metabolism
ATCvet code: QA12C

5.1 Pharmacodynamic properties

The product provides a supplementary source of a single nutrient, copper, over a prolonged period of time. Inadequate copper levels may be due to insufficient copper in the diet (primary copper deficiency) or secondary copper deficiency resulting from antagonistic effects of molybdenum and/or sulphur upon copper absorption.

5.2 Pharmacokinetic properties

The copper oxide needles are retained in the digestive tract of ruminants and gives a slow release of copper in an absorptive form, which gradually raises liver copper levels. The use of Copinox is appropriate both in primary and secondary deficiencies.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Porcine Gelatin
Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Sodium Lauryl Sulphate
Sunset Yellow (E110)
Erythrosine (E127)
Titanium Dioxide (E171)
Iron Oxide (E172)

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°C.
Protect from direct sunlight.
Protect from frost.
Keep the box tightly closed in order to protect from moisture.

6.5 Nature and composition of immediate packaging

Rectangular cardboard tray and lid with foam rubber lining individually shrink wrapped, containing 24 x 27 g maroon capsules.

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

Dispose of unused product, product containers and any waste in accordance with current practice for chemical waste disposal under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Animax Ltd.
Shepherds Grove West
Stanton
Suffolk
IP31 2AR
UK

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10834/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st August 2006

10 DATE OF REVISION OF THE TEXT