IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10966/012/001**
Case No: 7000763

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:

Vetoquinol UK Limited

Vetoquinol House, **Great Slade**, **Buckingham MK18 1PA**, **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:

Bomatak white-stripe 7.5% Pour-on Suspension

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 **26/10/2005**.

Signed on behalf of the Irish Medicines Board

_____

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

Bomatak White Stripe 7.5% Pour-on Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Oxfendazole	75	mg
Benzyl Alcohol (preservative)	52.3	mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Topical suspension.

4 CLINICAL PARTICULARS

Oxfendazole belongs to the benzimidazole family of anthelmintics and works by inhibiting tubulin synthesis in the parasite.

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Bomatak White Stripe is a broad spectrum topical anthelmintic suspension for the treatment and control of mature, immature and egg stages of all major gastrointestinal roundworms, lungworms and tapeworms in cattle, including *Ostertagia* spp. (adults, fourth stage larvae and inhibited/arrested larvae), *Haemonchus* spp., *Trichostrongylus* spp., *Nematodirus* spp., *Cooperia* spp. (adults and fourth stage larvae), *Oesophagostomum* spp., *Trichuris* spp., *Dictyocaulus* spp. and *Moniezia* spp.

4.3 Contraindications

None.

4.4 Special warnings for each target species

For external use only.

4.5 Special precautions for use

Do not apply to wet cattle and avoid applying when rain is likely within 30 minutes of application. Avoid applying to areas of skin where there is material such as mud covering the skin surface.

Dosing regimes:

The following are guidelines to regular dosing. As with other anthelmintics, it is important that they are used in the context of an effective animal husbandry system, using appropriate grassland management strategies.

Bought-in cattle:

Cattle should be dosed on arrival and held separately before admittance to the herd.

Young cattle and yearlings:

Dose animals as necessary during the grazing season. After dosing move animals to clean pasture where possible.

Type II Ostertagiasis:

For the prevention of this condition, dose in late autumn and house immediately.

It is recommended that veterinary advice be sought on suitable dosage regimes and stock management to achieve adequate parasite control and reduce the possibility of anthelmintic resistance developing. Similarly, if desired clinical effect is not achieved veterinary advice should be sought, since other diseases, nutritional imbalances or anthelmintic resistance may be involved.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Milk intended for human consumption must be discarded during treatment and for 8 days following the last treatment.

May be used in pregnant animals at standard dose rate.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

Shake thoroughly before use. For topical use only. Cattle: 10mg per kg bodyweight equivalent to 4ml per 30kg bodyweight. This product is formulated for external application to cattle only and should be applied along the midline of the back between the withers and the base of the tail using a proprietary applicator. Do not underdose. Care should be taken to estimate accurately the bodyweight of animals to be treated.

Check accuracy of pour on gun or applicator regularly. Draft animals into lines of similar bodyweight, then dose according to weight of the heaviest animal in the line. Cattle should not be treated if the hair or hide is wet. Rain falling less than 30 minutes after dosing may reduce efficacy. Avoid applying to areas of the skin where there is material such as mud covering the skin surface. Dosing equipment should be cleaned thoroughly before and after use. Dosing may be repeated at required intervals.

Re-dosing intervals vary depending on age of animals, degree of parasitism and type of worm.

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

In the case of overdose, no antidote is available and symptomatic relief should be given.

4.11 Withdrawal Period(s)

Meat: Cattle producing meat and offal for human consumption must not be slaughtered during or within 21 days of the last treatment.

Milk: Milk intended for human consumption must be discarded during treatment and for 8 days following the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Oxfendazole belongs to the benzimidazole family of anthelmintics and works by inhibiting tubulin synthesis in the parasite.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl Myristate
Sorbitan Monostearate
Canola Oil
Sodium Lignosulphonate
Benzyl Alcohol
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinaryis medicinal product as packaged for sale : 2 years

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

Supplied in 1 litre HDPE bottle and 5 litre HDPE jerrycan and a screw top closure. A HDPE graduated 250 ml dosing cup is provided.

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

Any 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

Vetoquinol UK Limited
Vetoquinol House
Great Slade
Buckingham Industrial Park
Buckingham
MK18 1PA
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10966/012/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26th October 2005

10 DATE OF REVISION OF THE TEXT