IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

10990/036/001
Case No: 7002254

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Univet Limited

Tullyvin, **Cootehill**, **Co. Cavan.**, **Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

SMB Powder

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **15/12/2006** until .

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

SMB Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	Quantity
Sulfadimidine	100.0 %w/w

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Monogastric calves.

4.2 Indications for use, specifying the target species

SMB Powder is for the treatment and control of infections in monogastric calves caused by organisms sensitive to Sulfadimidine.

4.3 Contraindications

Do not use in animals known to be sensitive to sulphonamides.
Local anaesthetics of the procaine group are antoginistic and should not be used during treatment.

4.4 Special warnings for each target species

As with all sulphonamides, prolonged treatment may give rise to Vitamin K deficiency, agranulocytosis and haemolytic anaemia and should therefore be avoided.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special Precautions to be taken by the Person Administering the Product to Animals

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

The procaine of procaine benzylpenicillin and of the procaine group of local anaesthetics is an analogue of PABA and will antagonise sulfonamides. There is interaction and antagonism between sulfonamides and vitamin B complex.

4.9 Amounts to be administered and administration route

For oral administration following suspension in drinking water. The required dose should be added to twice/three times its own volume of water and administered as an oral drench.

2g SMB Powder per 10kg on the first day of treatment, then 1 g per 10kg for a further 2 days only.

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

Prolonged treatment may lead to a risk of vitamin K deficiency, agranulocytosis and haemolytic anaemia.

4.11 Withdrawal Period(s)

Animals should not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption only after 28 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The specific mechanism underlying the basis of the pharmacological activity of Sulfadimidine is the inhibition of para-amino-benzoic acid. This inhibition prevents bacterial synthesis of folic acid, which is the metabolic stage in the synthesis of purines and ultimately of DNA. Sulfadimidine exerts a bacteriostatic effect.

Sulfadimidine is rapidly absorbed following oral administration. The sulfonamides as a group diffuse very widely into the tissues, penetrating into all fluids. With the exception of the blood brain barrier, all other natural barriers are passed and effective concentrations appear in all tissues, body cavities and secretions, including urine, bile and milk. The placenta is also crossed. Excretion is mainly via the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

None known.

6.3 Shelf-life

2 years.
The product must be administered immediately after suspension in water.

6.4 Special precautions for storage

Do not store above 25°C
Protect from light.

6.5 Nature and composition of immediate packaging

A white or almost white powder in metallised, heat-sealed 25g sachets.

*Presentations: Box containing 50 or 100 sachets.

*Not all presentations may be marketed.

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 national requirements.

7 MARKETING AUTHORISATION HOLDER

Univet Ltd
Tullyvin
Co Cavan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10990/36/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31st May 2002