IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10819/001/001**
Case No: 7001482

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:

Pharmalett A/S

Profilvej 1, **DK-6000 Kolding**, **Denmark**

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:

Diaproof-K Powder for Oral Solution

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 this

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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

Diaproof K Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances		
Glucose monohydrate	40.61%	w/w
Potassium chloride	2.67%	w/w
Sodium citrate	2.95%	w/w
Sodium chloride	4.64%	w/w
Sodium hydrogen carbonate	7.60%	w/w
Isphagula Husk	40.61%	w/w
Magnesium hydroxide	0.82%	w/w
Excipients		
Red ferric oxide (E172)	0.10%	w/w

3 PHARMACEUTICAL FORM

Powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Calves.

4.2 Indications for use, specifying the target species

For the treatment of diarrhoea in young calves.

4.3 Contraindications

None.

4.4 Special warnings for each target species

In severe cases of diarrhoea additional intravenous rehydration therapy may be necessary.

If diarrhoea persists for three to four days, a veterinary surgeon should be consulted.

Adequate colostrum should be fed to calves.

It is important that the dosages are strictly adhered to.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

None.

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

Diaproof K should not be used in conjunction with other electrolyte mixtures. It is not advisable to combine Diaproof K with the use of spasmolytic agents.

4.9 Amounts to be administered and administration route

For oral administration.

The usual dosage for young calves (about 35 kg) is given in the schedule below. One scoop contains 20 gr. Diaproof K.

Start - First Feeding - 3 scoops Diaproof K in 1.5 litre of water at 40 degrees C.

After 12 hours - Second Feeding - 3 scoops of Diaproof K in 1.5 litre of water at 40 degrees C.

After 24 hours - Third Feeding - 3 scoops of Diaproof K in 1.5 litre of water at 40 degrees C.

After 36 hours - Fourth Feeding - 2 scoops of Diaproof K in 0.75 litre of water at 40 degrees C + 0.75 litre of milk.

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

None.

4.11 Withdrawal Period(s)

Animals may be slaughtered for human consumption during treatment and following treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Diaproof-K is a mixture of glucose, electrolytes and Isphagula Husk. Isphagula Husk contains mucopolysaccharides, which form a gel in water. The mucopolysaccharides are used in combination with glucose and electrolytes in a concentration, also used in oral rehydration therapy. The combination of Isphagula Husk with electrolytes and glucose is an efficient preparation in rehydration therapy and treatment of diarrhoea. The mucopolysaccharides have a protective activity on the intestinal wall.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Red ferric oxide (E172)

6.2 Incompatibilities

None known.

6.3 Shelf-life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.
Store in a dry place.

6.5 Nature and composition of immediate packaging

Diaproof K is sold in polyethylene container of 1 kg, 2.5 kg and 0.4 kg containing a pinkish-brown granular powder.

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

Pharmalett A/S
Profilvej 1
6000 Kolding
Denmark

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10819/1/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004