

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10956/017/001**

Case No: 7004351

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:

Ballinskelligs Vet. Products Ltd

Ballinskelligs, Co. Kerry, 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:

Replenolyte (Concentrate) Oral Solution %v/v 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.

The authorisation, unless revoked, shall continue in force from **04/04/2008**.

Signed on behalf of the Irish Medicines Board

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

Replenolyte (Concentrate) Oral Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances:

| | |
|--------------------------------|-----------|
| Calcium Chloride Dihydrate | 0.5% w/v |
| Potassium Chloride | 1.5% w/v |
| Magnesium Chloride Hexahydrate | 0.45% w/v |
| Sodium Acetate Trihydrate | 12.5% w/v |
| Sodium Chloride | 8.0% w/v |
| Dextrose Monohydrate | 50% w/v |

Excipient:

| | |
|------------|------------|
| Ponceau 4R | 0.004% w/v |
|------------|------------|

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A clear, pink, aqueous, concentrated oral solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Sheep.

4.2 Indications for use, specifying the target species

For oral use to reverse the process of dehydration and electrolyte loss associated with scours in calves whether due to nutritional or infectious causes. To reduce scouring in bought-in calves. To reverse hypoglycaemia and aid recovery in cases of pregnancy toxemia in ewes.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Do not hold diluted solution for longer than 24 hours.

Allow animals free access to water.

If the condition fails to improve, consult a veterinary practitioner. In severe cases of dehydration, additional intravenous rehydration therapy may be necessary. In such cases, consult a veterinary practitioner.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

This product can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration only.

Calves:

Prior to use, dilute one part of concentrate to twenty parts with water.

As a guide:-

50 ml conc. to 1 litre with water.

100 ml conc. to 2 litres with water.

200 ml conc. to 4 litres with water.

Scouring Calves: Withdraw all milk and milk replacer.

Administer 2 litres of dilute Replenolyte twice daily for 2 days (four feeds).

For the next 4 feeds use 1 litre of diluted Replenolyte and 1 litre of milk or milk replacer. Thereafter feed as normal.

Sheep: In cases of pregnancy toxaemia in sheep 100ml of undiluted product should be administered in a suitable drenching bottle. Treatment should be repeated at 4-8 hour intervals as required.

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

The product is intended to replace electrolyte deficiency and overdosage within the recommended guidelines is unlikely.

4.11 Withdrawal Period(s)

Meat: Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

For oral use to reverse the process of dehydration and electrolyte loss.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ponceau 4R

Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

The diluted product should be used within 24hrs.

Discard any unused diluted solution.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

1L, 2.5L, 5L plastic containers with aluminium foil seal and tamper evident screw cap

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Tairgi Tread-Lia Baile na Sceilge Teo,
(Ballinskelligs Veterinary Products),
Ballinskelligs,
Killarney,
Co. Kerry,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10956/17/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2001.

1st October 2006.

10 DATE OF REVISION OF THE TEXT

4th April 2008