

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10999/054/001**
Case No: 7001663

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:

Norbrook Laboratories Limited

Station Works, Newry, Co. Down BT35 6JP

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:

Life Aid Xtra 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.

The authorisation,unless revoked, shall continue in force from **03/04/2009**.

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

Life Aid Xtra Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

Sodium citrate	4.681	% w/w
Sodium acetate	3.917	% w/w
Sodium propionate	2.293	% w/w
Sodium chloride	5.589	% w/w
Potassium chloride	3.559	% w/w
Potassium dihydrogen orthophosphate	1.624	% w/w
Glucose (anhydrous)	75.237	% w/w
Sunset yellow	0.1	% w/w

On reconstitution in 2 litres of water the available concentrations are as follows:

Sodium	90 mmol/l
Potassium	25 mmol/l
Chloride	60 mmol/l
Phosphate	5 mmol/l
Propionate	10 mmol/l
Acetate	20 mmol/l
Citrate	6.67 mmol/l
Dextrose	175 mmol/l

The propionate, acetate and citrate ions together yield 50 mmol/l bicarbonate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.
A pink powder that forms an orange solution on mixing with water.

4 CLINICAL PARTICULARS

4.1 Target Species

Calves.

4.2 Indications for use, specifying the target species

Life Aid Xtra is an oral rehydration product indicated for the reversal of the processes of dehydration, electrolyte loss and acidosis associated with scour in calves whether due to nutritional, bacterial, viral or cryptosporidial causes.

4.3 Contraindications

None.

4.4 Special warnings for each target species

In severe cases some calves may require additional i.v. rehydration therapy. In such cases consult a veterinary surgeon. If condition fails to improve after 4 days consult a veterinary surgeon.

4.5 Special precautions for use

Special precautions for use in animals

Keep feeding utensils clean and avoid over-feeding.

Adequate colostrum should have been fed to calves.

Normal feeding should be resumed after the course of treatment.

Do not use solution contaminated by foreign material.

Discard any unused solution after 24 hours.

Special Precautions to be taken by the Person Administering the 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

None known.

4.9 Amounts to be administered and administration route

For oral administration only.

Dosage: Prepare a fresh solution before each dose: dissolve the contents of one sachet in 2 litres (3½ pints) of warm water.

Administration: All milk and milk replacer is withdrawn on first signs of scour. Two litres of the solution, freshly prepared as directed, is given twice daily for 2 days. The solution provides an adequate source of nutrients and electrolytes which are readily absorbed. For the next 4 feeds (2 days) 1 litre of solution and 1 litre of milk replacer is administered. Thereafter normal diet is resumed. If symptoms are severe, the solution may be fed 3 or 4 times daily. The solution may be given for a maximum of 4 days only, when administered on its own.

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

Not applicable.

4.11 Withdrawal Period(s)

Meat - zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Oral electrolytes and carbohydrates
ATCvet Code: QA07CQ02

5.1 Pharmacodynamic properties

Life Aid Xtra is formulated to primarily correct a plasma volume deficit and acidosis. It also provides potassium, to counteract the decreasing intracellular potassium content, and dextrose as an energy source.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sunset Yellow (E110)
Silicon Dioxide

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after reconstitution according to directions: 24 hours

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

A paper/aluminium foil laminate lined with low density polyethylene and supplied in white polypropylene buckets of 12 and 48 sachets. Each sachet contains not less than 83.74 g.

Not all pack sizes may be marketed.

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

Norbrook Laboratories Limited,
Station Works,
Newry,
Co. Down, BT35 6JP,
Northern Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/054/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

8th February 2008

10 DATE OF REVISION OF THE TEXT

3rd April 2009