1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Effydral Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains :

Active substance

Sodium chloride	2.34	g
Potassium chloride	1.12	g
Sodium hydrogen carbonate	6.72	g
Anhydrous citric acid	3.84	g
Lactose monohydrate	32.44	g
Glycine	2.25	g

When one Effydral tablet is dissolved in 1 litre of water, the resulting isotonic oral rehydration solution has the following composition:

Constituent	(mmol/l)
Sodium	120
Potassium	15
Chloride	55
Bicarbonate + citrate	80*
Lactose	90**
Glycine	30

* Total alkali expressed as bicarbonate equivalents
** 90 mmol lactose is equivalent to 180 mmol glucoseFor a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent tablet.

4 CLINICAL PARTICULARS

4.1 Target Species

Calves

4.2 Indications for use, specifying the target species

Effydral solution corrects dehydration, electrolyte loss and metabolic acidosis, particularly when these disturbances arise as a consequence of diarrhoea. Effydral has been specially developed for the treatment of diarrhoea in calves.

4.3 Contraindications

If the gastro-intestinal tract is completely obstructed, great care should be taken when administering oral solutions.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

For oral administration only.

Always use clean water and equipment when preparing Effydral solution. Replace with fresh solution every 24 hours.

Follow the instructions for use exactly. Use of a too-dilute Effydral solution will have a reduced efficacy while use of a too-concentrated solution may result in osmotic diarrhoea. If a too-concentrated solution is fed, ensure that the animal has free access to drinking water.

Ensure that newborn animals receive adequate colostrum.

In very severe cases of dehydration additional intravenous fluid therapy may be required with an appropriate parenteral solution.

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

For animal treatment only.
Oral rehydration products comparable to Effydral are widely used in human medicine. Since the ingredients of Effydral are all natural foodstuffs, no public health problems are anticipated.

4.6 Adverse reactions (frequency and seriousness)

When used according to the instructions, no side-effects have been observed or are to be expected.

4.7 Use during pregnancy, lactation or lay

Although Effydral is only indicated for the treatment of young animals, the use of Effydral during gestation and lactation carries no known additional risks. The handling of pregnant animals carries its own inherent risks.

4.8 Interaction with other medicinal products and other forms of interaction

No known interactions.

4.9 Amounts to be administered and administration route

One litre of ready-to-use Effydral solution is prepared by adding one effervescent tablet to 1 litre lukewarm (circa 37^{o}C) water. The solution should be made up freshly just prior to feeding, using clean water and equipment.

Treatment should commence as soon as diarrhoea is noticed. Instead of feeding milk or milk replacer, feed 2 or 3 litres of Effydral solution twice daily for two days. During the next two days, feed 1 or 1.5 litres Effydral solution, mixed with an equal quantity of milk or milk replacer. Normal feeding can then usually be resumed.

If symptoms persist, consult your veterinarian about further treatment.

In cases of severe dehydration, the Effydral solution should be administered in 3 or 4 feeds per day. If necessary, Effydral solution can be administered by stomach tube.
If necessary, Effydral solutions can be fed exclusively for up to 4 days without harmful effects.

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

See under 4.5 above.

4.11 Withdrawal period(s)

Meat and offal: Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Phamacotherapeutic group: Eletrolyte solutions. ATCvet code: QB05XA

5.1 Pharmacodynamic properties

Effydral solution corrects dehydration, electrolyte loss and metabolic acidosis, particularly when these disturbances arise as a consequence of diarrhoea.

The physiological basis of the effectiveness of oral rehydration solutions is the coupled transport of sodium and glucose, galactose, glycine or other small organic molecules.

Water absorption through the intestine, itself a passive process, is the result of active sodium absorption.

Studies in animals (including humans) have demonstrated that the maximal uptake of sodium, and thus water, occurs when the ratio of the organic molecules to sodium is between 1:1 and 2:1.
Complete oral rehydration solutions must also contain potassium, chloride and alkalizing agents such as bicarbonate or bicarbonate precursors (e.g. citrate), to replace losses arising as a result of the diarrhoea. Bicarbonate and citrate also enhance the absorption of water and sodium.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C. Once dissolved in water store in a refrigerator (2°C - 8°C) for up to 24 hours. Any medicated water which is not consumed within 24 hours should be discarded.

6.5 Nature and composition of immediate packaging

Aluminium tubs covered with aluminium foil containing a round, white, effervescent tablet with flat end surfaces and bevelled edges. The diameter is about 52 mm and the height is about 19 mm. The mean tablet weight is about 48.7 g. One cardboard box contains 48 tablets packed in inner cartons of 6 x 8 tablets.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, where appropriate

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

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
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8 MARKETING AUTHORISATION NUMBER(S)

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9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 8th February 2009

10 DATE OF REVISION OF THE TEXT

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