SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Effydral Effervescent Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:	**Quantity (g/tablet)**
Sodium Chloride	2.34
Potassium Chloride	1.12
Sodium Bicarbonate	6.72
Citric Acid Anhydrous	3.84
Lactose Monohydrate	32.44
Glycine	2.25

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

Constituent	**Quantity (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 glucose

Excipient(s):

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Effervescent tablet
White round tablet with a smooth surface

4. CLINICAL PARTICULARS

4.1 Target species

Effydral has been specially developed for the treatment of

diarrhoea in calves and pigs.

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.

4.3 Contraindications

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

4.4 Special warnings for each target species

Wash hands after use.

4.5 Special precautions for use

(i) Special precautions for use in animals

Solutions should be prepared using clean water and feeding utensils should be kept clean. Replace with fresh solution every 24 hours.

If Effydral is administered in too concentrated a solution to an animal, free access to drinking water should be provided.

Whenever possible adequate colostrum should be fed to animals.

Avoid over feeding of milk or milk replacer.

For oral administration only.

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

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

None.

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

None known.

4.9 Amounts to be administered and administration route

Effydral is intended for oral administration only.

Effydral solution is prepared by adding one effervescent tablet to 1 litre lukewarm (about 37°C) water. The solution should be freshly made up just prior to feeding, using clean water and utensils.

If solution has been stored in a refrigerator (2-8°C), gently warm to 37°C before administration.

Calves

Calves with diarrhoea: Treatment should commence immediately diarrhoea is noticed. Withdraw milk or milk replacer and feed 2 or 3 litres of Effydral solution, depending on calf size or severity of diarrhoea, twice daily for two days.

During the next two days, feed 1 or 1.5 litres of Effydral solution mixed with an equal quantity of milk or milk replacer. Normal feeding can then usually be resumed.

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

Bought-in calves: Instead of milk or milk replacer, the first feed on arrival should consist of 2 litres of Effydral solution. The second feed should contain 1 litre of Effydral solution mixed with 1 litre of milk or milk replacer. Thereafter feed as normal.

Pigs

Birth to weaning: When scour occurs, make Effydral available *ad libitum* in a clean utensil. The amount consumed per pig depends on age.

Weaned pigs: Allow *ad libitum* consumption up to a maximum of 1 litre per pig per day. Provide untreated water at all times.

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

Refer to section 4.6

4.11 Withdrawal period(s)

Zero days.

5. PHARMACOLOGICAL 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 alkalising agents such as bicarbonate or bicarbonate precursors (eg citrate), to replace losses arising as a result of the diarrhoea. Bicarbonate and citrate also enhance the absorption of water and sodium.

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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.
Shelf-life after dilution or reconstitution according to directions: 24 hours.

6.4 Special precautions for storage

Do not store above 25°C. Once dissolved in water, store in a refrigerator (2-8°C). 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. One cardboard box contains 48 individually packed tablets.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
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8. MARKETING AUTHORISATION NUMBER

Vm 42058/4056

9. DATE OF FIRST AUTHORISATION

01 March 1993

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 28 August 2020