

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Inner carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Effydral® Effervescent Tablet

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Sodium chloride	2.34 g
Potassium chloride	1.12 g
Sodium bicarbonate	6.72 g
Citric Acid (anhydrous)	3.84 g
Lactose monohydrate	32.44 g
Glycine	2.25 g

3. PHARMACEUTICAL FORM

Effervescent Tablet

4. PACKAGE SIZE

8 Tablets

5. TARGET SPECIES

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6. INDICATION(S)

Rapid rehydration in an effervescent tablet.

For uses: see leaflet.

7. METHOD AND ROUTE OF ADMINISTRATION

For oral administration only.

Dissolve 1 tablet in 1 litre of water.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNINGS, IF NECESSARY

If signs of disease persist or appear, consult a veterinary surgeon.

User Warnings: Wash hands after use.

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Once dissolved in water, store in a refrigerator (2 – 8°C).

Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of unused solution in slurry or dirty water. Dispose of unused tablets and empty packaging in the farm refuse.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

AVM-GSL

For animal treatment only

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4056

17. MANUFACTURER’S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Outer carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Effydral® Effervescent Tablet

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition per effervescent tablet

Sodium chloride	2.34 g
Potassium chloride	1.12 g
Sodium bicarbonate	6.72 g
Citric Acid (anhydrous)	3.84 g
Lactose monohydrate	32.44 g
Glycine	2.25 g

Composition of solution after dissolving one tablet in one litre of water

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

* The total quantity of alkali is expressed in bicarbonate equivalents

** 90 mmol lactose is equivalent to 180 mmol glucose

3. PHARMACEUTICAL FORM

Effervescent Tablet

4. PACKAGE SIZE

48 Tablets

Box contains 48 tablets individually packed in aluminium containers.

5. TARGET SPECIES

Calves and pigs

6. INDICATION(S)

Rapid rehydration in an effervescent tablet.

For oral rehydration therapy during the treatment and prevention of diarrhoea in calves and pigs.

The composition of Effydral is such that it rapidly and effectively corrects dehydration, electrolyte loss and metabolic acidosis.

For use: see leaflet.

7. METHOD AND ROUTE OF ADMINISTRATION

For oral use only.

Dissolve one effervescent tablet in one litre of lukewarm (about 37°C) water. Discard any unused solution after 24 hours.

Replace with fresh solution every 24 hours.

8. WITHDRAWAL PERIOD

Meat withdrawal period - zero days.

9. SPECIAL WARNINGS, IF NECESSARY

For oral administration only.

Solutions should be prepared using clean water and feeding utensils should be kept clean.

Whenever possible adequate colostrum should be fed to calves.

If signs of disease persist or appear, consult a veterinary surgeon.

If Effydral solution is administered in too concentrated a solution to calves or pigs, free access to drinking water should be provided.

Avoid over feeding of milk or milk replacer to calves.

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

If the gastrointestinal tract is completely obstructed care should be taken when administering oral solutions.

User Warnings: Wash hands after use.

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Once dissolved in water, store in a refrigerator (2 – 8°C).

Any medicated water not consumed within 24 hours should be discarded.

Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of unused solution in slurry or dirty water. Dispose of unused tablets and empty packaging in the farm refuse.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

AVM-GSL

For animal treatment only

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4056

17. MANUFACTURER’S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {Foil blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Effydral® Effervescent Tablet

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Sodium chloride	2.34 g
Potassium chloride	1.12 g
Sodium bicarbonate	6.72 g
Citric acid (anhydrous)	3.84 g
Lactose monohydrate	32.44 g
Glycine	2.25 g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

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4. ROUTE(S) OF ADMINISTRATION

For oral use only

Dissolve 1 tablet in 1 litre of water.

5. WITHDRAWAL PERIOD

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6. BATCH NUMBER

Lot:

7. EXPIRY DATE

Exp:

Discard date:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

Keep out of reach and sight of children.

For animal treatment only

Do not store above 25°C.

Keep container in outer carton.

UK: Zoetis UK Limited, Surrey
Vm 42058/4056

AVM-GSL

PACKAGE LEAFLET FOR:

Effydral® Effervescent Tablet

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Batch release site not currently listed

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Effydral® Effervescent Tablet

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

An effervescent, rapidly dissolving, white tablet individually packed in an aluminium container.

Each tablet contains:

Sodium chloride	2.34 g
Potassium chloride	1.12 g
Sodium bicarbonate	6.72 g
Citric Acid (anhydrous)	3.84 g
Lactose monohydrate	32.44 g
Glycine	2.25 g

The addition of one Effydral tablet to 1 litre of water produces an isotonic, oral rehydration solution with the following composition:

Sodium	120 mmol
Potassium	15 mmol
Chloride	55 mmol
Bicarbonate + citrate	80 mmol*
Lactose	90 mmol#
Glycine	30 mmol

* Total alkali expressed as bicarbonate equivalents.

90 mmol lactose is equivalent to 180 mmol glucose.

4. INDICATIONS

Effydral is specially formulated to provide rapid correction of dehydration, electrolyte loss and metabolic acidosis particularly when these disturbances arise as a consequence of diarrhoea.

Calves: Effydral is recommended to reverse the process of dehydration and loss of electrolytes following diarrhoea resulting from bacteria such as E.coli or viruses such as rotavirus.

It is also indicated to reduce the incidence of diarrhoea in bought-in calves.

Pigs: Effydral is recommended to reverse the process of dehydration and loss of electrolytes following pre and post weaning diarrhoea resulting from bacteria such as E.coli or viruses such as rotavirus.

To encourage fluid intake and prevent dehydration and setback after periods of stress eg. weaning, transporting, etc.

5. CONTRAINDICATIONS

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

Avoid over-feeding of milk or milk replacer.

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

6. ADVERSE REACTIONS

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7. TARGET SPECIES

Calves and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Effydral is intended for oral administration only.

Effydral solution is prepared by adding 1 effervescent tablet to 1 litre of luke warm (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.

DOSAGE

Calves

(i) 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 2 days. During the next 2 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 Effydral solution should be administered in 3 or 4 feeds per day. If necessary the solution may be administered by stomach tube. Normally, calves can be fed Effydral solution exclusively for up to 4 days without harmful effects.

(ii) 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

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

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

9. ADVICE ON CORRECT ADMINISTRATION

If Effydral is administered in too concentrated a solution to a calf or pig, free access to drinking water should be provided.

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

10. WITHDRAWAL PERIOD(S)

Meat withdrawal period - zero days.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Once dissolved in water store in a refrigerator (2-8°C).

Any medicated water not consumed within 24 hours should be discarded.

Keep container in outer carton.

When the product is dissolved, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be

discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Whenever possible adequate colostrum should be fed to calves and pigs.

If signs of disease persist or appear, consult a veterinary surgeon.

User Warnings: Wash hands after use.

For animal treatment only

Keep out of reach and sight of children.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of unused solution in slurry or dirty water. Dispose of unused tablets and empty packaging in the farm refuse.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

Cardboard carton containing 48 tablets, each tablet individually packed in an aluminium container closed with aluminium foil.

The vital attributes of an effective oral rehydration solution are that it should contain appropriate amounts of sodium and small organic molecules like glucose and galactose to ensure its complete absorption. It should also contain sufficient sodium bicarbonate or bicarbonate precursor, to enable restoration of the extracellular fluid volume (and therefore, circulatory volume) and correction of the metabolic acidosis. Efficacy effectively combats dehydration, electrolyte losses (especially hyponatraemia) and metabolic acidosis which are the most serious consequences of diarrhoea.

AVM-GSL

Vm 42058/4056

Approved 28 August 2020

