PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZORABEL 50 mg/ml oral suspension for pigs [CZ, DK, ES, HU, IE, PL, PT, SK]
Toltrazuril

ZORABEL vet 50 mg/ml Oral Suspension for pigs [SE]
Toltrazuril

BUSERIL 50 mg/ml oral suspension for pigs [FR]
Toltrazuril

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Toltrazuril 50 mg

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

100 ml
250 ml
15 x 250 ml

5. TARGET SPECIES

Pigs (Piglet 3 – 5 days old)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The oral suspension must be shaken well before use until complete resuspension. The suspension should be white or cream.Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 73 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once use within: 3 months
Once use by:

[PL]
Termin ważności (EXP)

11. SPECIAL STORAGE CONDITIONS

Not applicable.

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

Disposal: read package leaflet.

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

For animal treatment only - to be supplied only on veterinary prescription.

[PL]
Wyłącznie dla zwierząt.Wydawany z przepisu lekarza– Rp. Do podawania pod nadzorem lekarza weterynarii.

[ES]: To be administered by the veterinarian or under veterinarian supervision.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VETPHARMA ANIMAL HEALTH, S.L
Les Corts, 23
08028 Barcelona
SPAIN

Distributed by:

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch
[PL]
Nr serii (LOT)

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZORABEL 50 mg/ml oral suspension for pigs [CZ, DK, ES, HU, IE, PL, PT, SK]
Toltrazuril

ZORABEL vet 50 mg/ml Oral Suspension for pigs [SE]
Toltrazuril

BUSERIL 50 mg/ml oral suspension for pigs [FR]
Toltrazuril

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Toltrazuril 50 mg

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Pigs (Piglet 3 – 5 days old)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The oral suspension must be shaken well before use until complete resuspension. The suspension should be white or cream. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 73 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once use within:: 3 months
Once use by:

[PL]
Termin ważności (EXP)

11. SPECIAL STORAGE CONDITIONS

Not applicable.

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

Disposal: read package leaflet.

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

For animal treatment only - to be supplied only on veterinary prescription.

[PL]
Wyłącznie dla zwierząt.Wydawany z przepisu lekarza– Rp. Do podawania pod nadzorem lekarza weterynarii.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VETPHARMA ANIMAL HEALTH, S.L
Les Corts, 23
08028 Barcelona
SPAIN

Distributed by:

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch

[PL]
Nr serii (LOT)

PACKAGE LEAFLET

ZORABEL 50 mg/ml oral suspension for pigs [CZ, DK, ES, HU, IE, PL, PT, SK]

ZORABEL vet 50 mg/ml Oral Suspension for pigs [SE]

BUSERIL 50 mg/ml oral suspension for pigs [FR]

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

Marketing authorisation holder:
VETPHARMA ANIMAL HEALTH, S.L
Les Corts, 23
08028 Barcelona
SPAIN

Manufacturer responsible for the batch release:
MEVET S.A.U
Pol. Ind. El Segre, p. 409-410
25191 Lleida
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZORABEL 50 mg/ml oral suspension for pigs [CZ, DK, ES, HU, IE, PL, PT, SK]
Toltrazuril

ZORABEL vet 50 mg/ml Oral Suspension for pigs [SE]
Toltrazuril

BUSERIL 50 mg/ml oral suspension for pigs [FR]
Toltrazuril

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:
Toltrazuril 50 mg

Excipients:
Sodium Benzoate (E 211) 2.1 mg
Sodium Propionate (E 281) 2.1 mg
Other excipients, q.s.

White or cream suspension

4. INDICATION(S)

For the prevention of clinical signs of coccidiosis in neonatal piglets (3 – 5 days old) on farms with a confirmed history of coccidiosis caused by *Isospora suis.*

5. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

[PL] Alternatively you can report via your national reporting system {national system details}

7. TARGET SPECIES

Pigs (Piglet 3 – 5 days old)

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

Oral use.
Individual animal treatment.

Treat each pig to be treated on day 3 – 5 of life with a single oral dose of 20 mg toltrazuril/kg body weight (corresponding to 0.4 ml veterinary medicinal product per kg body weight).

9. ADVICE ON CORRECT ADMINISTRATION

Due to the small volumes requires to treat individual piglets, use of dosing equipment with a dose accuracy of 0.1 ml is recommended.

The weight of animal should be accurately determined before treatment.

The oral suspension must be shaken well before use until complete resuspension. The suspension should be white or cream.
Treatment during an outbreak will be of limited value for the individual piglet because of damage to the small intestine having already occurred.

10. WITHDRAWAL PERIOD

Meat and offal: 73 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.
Shelf-life after first opening the container: 3 months

12. SPECIAL WARNING(S)

Special warnings for each target species
As with any antiparasiticide, frequent and prolonged use of an antiprotozoal of the same class of active substance and underdosing due to underestimation of the live weigh may result in the development of resistance.

It is recommended to treat all piglets in a litter.

Hygienic measures may reduce the risk of porcine coccidiosis. It is therefore, recommended to improve concomitantly the hygienic conditions in the concerned facility, particularly dryness and cleanliness.

To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.

To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.

Special precautions for use in animals:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to toltrazuril, or any of the excipients, should avoid contact with the veterinary medicinal product.
Avoid skin and eye contact with the product.
In case of accidental exposure**,** wash any splashes from skin or eyes immediately with water.
Do not eat, drink or smoke whilst using the product.

Interaction with other medicinal products and other forms of interaction:
None known, e.g there is no interaction in combination with iron supplementation

Overdose (symptoms, emergency procedures, antidotes), if necessary
A threefold overdose is well tolerated by healthy piglets.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicines.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<Date of last renewal> <{DD/MM/YYYY}><{DD/month/YYYY}>

15. OTHER INFORMATION

The bottles are placed into cardboard box, container of 1 unit of 100 ml bottle, container of 1 unit of 250 ml bottle and clinical container of 15 units of 250 ml bottles.
Not all pack sizes may be marketed.
[ES]
For animal treatment only. To be supplied only on veterinary prescription.
Administration under control or supervision of a veterinary surgeon.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET COMBINED LABEL AND PACKAGE LEAFLET

LABEL-LEAFLET 1 L

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

Marketing authorisation holder:
VETPHARMA ANIMAL HEALTH, S.L
Les Corts, 23
08028 Barcelona
SPAIN

Manufacturer responsible for batch release:
MEVET S.A.U
Pol. Ind. El Segre, P.409-410
25191 Lleida
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZORABEL 50 mg/ml oral suspension for pigs [CZ, DK, ES, HU, IE, PL, PT, SK]
Toltrazuril

ZORABEL vet 50 mg/ml Oral Suspension for pigs [SE]
Toltrazuril

BUSERIL 50 mg/ml oral suspension for pigs [FR]
Toltrazuril

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substance:
Toltrazuril 50 mg

Excipients:
Sodium Benzoate (E 211) 2.1 mg
Sodium Propionate (E 281) 2.1 mg

White or cream suspension

4. PHARMACEUTICAL FORM

Oral suspension

5. PACKAGE SIZE

1 L

6. INDICATIONS

For the prevention of clinical signs of coccidiosis in neonatal piglets (3 – 5 days old) on farms with a confirmed history of coccidiosis caused by *Isospora suis.*

7. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.

8. ADVERSE REACTIONS

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

[PL] Alternatively you can report via your national reporting system {national system details}

9. TARGET SPECIES

Pigs (Piglet 3 – 5 days old)

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

Oral use.
Individual animal treatment.

Treat each pig to be treated on day 3 – 5 of life with a single oral dose of 20 mg toltrazuril/kg body weight (corresponding to 0.4 ml veterinary medicinal product per kg body weight).

11. ADVICE ON CORRECT ADMINISTRATION

Due to the small volumes requires to treat individual piglets, use of dosing equipment with a dose accuracy of 0.1 ml is recommended.

The weight of animal should be accurately determined before treatment.

The oral suspension must be shaken well before use until complete resuspension. The suspension should be white or cream.
Treatment during an outbreak will be of limited value for the individual piglet because of damage to the small intestine having already occurred.

12. WITHDRAWAL PERIOD

Meat and offal: 73 days

13. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

Shelf-life after first opening the container: 3 months
Once broached,/opened, use by…

14. SPECIAL WARNINGS

Special warnings for each target species:

As with any antiparasiticide, frequent and prolonged use of an antiprotozoal of the same class of active substance and underdosing due to underestimation of the live weight may result in the development of resistances.

It is recommended to treat all piglets in a litter.

Hygienic measures may reduce the risk of coccidiosis. It is therefore recommended to improve concomitantly the hygienic conditions in the concerned facility, particularly dryness and cleanliness.

To obtain maximum benefit, animals should be treated before the expected onset of clinical signs, i.e. in the prepatent period.

To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.

Treatment during an outbreak will be of limited value to the individual piglet because of damage to the small intestine having already occurred.

Special precautions for use in animals

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to toltrazuril, or any of the excipients, should avoid contact with the veterinary medicinal product.
Avoid skin and eye contact with the product.
In case of accidental exposure, wash any splashes from skin or eyes immediately with water.
Do not eat, drink or smoke whilst using the product.

Interaction with other medicinal products and other forms of interaction

None known, e.g there is no interaction in combination with iron supplementation

Overdose (symptoms, emergency procedures, antidotes):

A threefold overdose is well tolerated by healthy piglets.

Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicines.

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

16. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<Date of last renewal> <{DD/MM/YYYY}><{DD/month/YYYY}>

17. OTHER INFORMATION

The veterinary medicinal product is packaged in high polyethylene density bottle with high-density polyethylene cap with strapping and welding disk of 100 ml, 250 ml or 1L.
The bottles are placed into cardboard box, container of 1 unit of 100 ml bottle, container of 1 unit of 250 ml bottle and clinical container of 15 units of 250 ml bottles.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

For animal treatment only.
To be supplied only on veterinary prescription.
[ES]: Administration under control or supervision of a veterinary surgeon.

18. The words "For animal treatment only" and conditions or restrictions regarding supply and use, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

19. The words "Keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

EXP {month/year}

Once use within: 3 months
Once use by:

21. Marketing authorisation number(s)

22. Manufacturer's batch number

Lot {number}