PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZORABEL 50 mg/ml oral suspension for pigs [CZ, DE, DK, ES, EE, , HU, LT, LV, PL, PT, SK, UK]
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 AND OTHER SUBSTANCES

One ml contains:

Active substance:

Toltrazuril	50 mg

Excipients:

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

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. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use
Read the package leaflet before use.

8. 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}
Shelf-life after first opening the immediate packaging: 3 months

[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)

Vm 32509/4014

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, DE, DK, ES, EE, , HU, LT, LV, PL, PT, SK, UK]
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 AND OTHER SUBSTANCES

One ml contains:

Active substance:

Toltrazuril	50 mg

Excipients:

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

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. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use
Read the package leaflet before use.

8. 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}
Shelf-life after first opening the immediate packaging: 3 months
Once broached,/opened, 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)

Vm 32509/4014

17. MANUFACTURER'S BATCH NUMBER

Batch

[PL]
Nr serii (LOT)

PACKAGE LEAFLET

ZORABEL 50 mg/ml oral suspension for pigs [CZ, DE, DK, ES, EE, , HU, LT, LV, PL, PT, SK, UK]
Toltrazuril
ZORABEL vet 50 mg/ml Oral Suspension for pigs [SE]
Toltrazuril
BUSERIL 50 mg/ml oral suspension for pigs [FR]
Toltrazuril

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

Distributed by:

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZORABEL 50 mg/ml oral suspension for pigs [CZ, DE, DK, ES, EE, , HU, LT, LV, PL, PT, SK, UK]
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)

One ml contains:

Active substance:
Toltrazuril 50 mg

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

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

None.

6. ADVERSE REACTIONS

None known.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (Piglet 3 – 5 days old)

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

For oral use.
Individual animal treatment.

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 oral suspension 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 oral suspension must be shaken well before use.

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: 73days

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 after the expiry date stated on the label.
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 precautions for use in animals:
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 alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.

As with any antiparasiticide, frequent and repeated use of antiprotozoals from the same class may lead to the development of resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known sensitivity to toltrazuril, or any of the excipients, should avoid contact with this product.
Avoid skin and eye contact with the product.
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

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. 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.

PARTICULARS TO APPEAR ON THE 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

Distributed by:

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

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Active substance:

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Excipients:

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4. INDICATION(S)

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5. CONTRAINDICATIONS

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6. ADVERSE REACTIONS

None known.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

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10. WITHDRAWAL PERIOD

Meat and offal: 73days

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

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Special precautions for use in animals

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User Warnings

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15. OTHER INFORMATION

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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.

Marketing Authorisation Number(s)

Lot {number}

Approved: 20 October 2017