LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Espacox 50 mg/ml oral suspension for pigs.
Toltrazuril

2. STATEMENT OF ACTIVE SUBSTANCES

Toltrazuril 50 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Pigs (Piglets, 3 - 5 days old)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Shake well before use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Meat and offal: 73 days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 6 months.
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

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

Dispose of waste material in accordance with local requirements.

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.

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

Industrial Veterinaria, S.A.
Esmeralda 19
E-08950 Esplugues de Llobregat
Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 36547/4004

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Espacox 50 mg/ml oral suspension for pigs
Toltrazuril

2. STATEMENT OF ACTIVE SUBSTANCES

Toltrazuril 50 mg/ml

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Pigs (Piglets, 3 - 5 days old)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Shake well before use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Meat and offal: 73 days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 6 months.
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

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

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.

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

Industrial Veterinaria, S.A.
Esmeralda 19
E-08950 Esplugues de Llobregat
Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 36547/4004

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Espacox 50 mg/ml oral suspension for pigs

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

Marketing authorisation holder:
Industrial Veterinaria, S.A.
Esmeralda 19
E-08950 Esplugues de Llobregat
Barcelona
Spain

Manufacturer responsible for batch release:
Industrial Veterinaria, S.A.
Esmeralda 19
08950 Esplugues de Llobregat (Barcelona) Spain

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Espacox 50 mg/ml oral suspension for pigs
Toltrazuril

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

Each ml contains:

Active substance:
Toltrazuril 50 mg

Excipients:
Sodium benzoate (E211) 2.1 mg
Sodium propionate (E281) 2.1 mg

White or yellowish 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 *Cystoisospora suis* (*Isospora suis*).

5. CONTRAINDICATIONS

Do not use in cases of 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.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Pigs (Piglets, 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 required to treat individual piglets, use of dosing equipment with a dose accuracy of 0.1 ml is recommended.
The oral suspension must be shaken 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.
The weight of animal should be accurately determined before treatment.

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 after EXP. The expiry date refers to the last day of that month.

Shelf-life after first opening the container: 6 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 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:
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to toltrazuril, or any of the excipients, should avoid contact with the veterinary medicinal product.
The product may cause irritation if it comes into contact with the skin or eyes.
Avoid skin and eye contact with the product.
In case of accidental exposure, wash any splashes from skin or eyes immediately with water.
Wash hands and exposed skin after use.
Do not eat, drink or smoke whilst using the product.

Interaction with other medicinal products and other forms of interaction:
None known.
There is no interaction in combination with iron supplementation

Overdose (symptoms, emergency procedures, antidotes):
No signs of intolerance were observed in piglets up to threefold overdose.

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

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 product should be disposed of in accordance with local requirements.
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

January 2021

15. OTHER INFORMATION

Package sizes:
Bottle of 1 L
Cardboard box with 1 bottle of 250 ml
Not all pack sizes may be marketed.

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

LABEL 1 l

Espacox 50 mg/ml oral suspension for pigs

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

Marketing authorisation holder:
Industrial Veterinaria, S.A.
Esmeralda 19
E-08950 Esplugues de Llobregat
Barcelona
Spain

Manufacturer responsible for batch release:
Industrial Veterinaria, S.A.
Esmeralda 19
08950 Esplugues de Llobregat (Barcelona) Spain

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Espacox 50 mg/ml oral suspension for pigs
Toltrazuril

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

Each ml contains:

Active substance:
Toltrazuril 50 mg

Excipients:
Sodium benzoate (E211) 2.1 mg
Sodium propionate (E281) 2.1 mg

White or yellowish suspension

4. PHARMACEUTICAL FORM

Oral suspension

5. PACKAGE SIZE

1 L

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 *Cystoisospora suis* (*Isospora suis*).

7. CONTRAINDICATIONS

Do not use in cases of 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.

Alternatively you can report via your national reporting system {national system details}.

9. TARGET SPECIES

Pigs (Piglets, 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 required to treat individual piglets, use of dosing equipment with a dose accuracy of 0.1 ml is recommended.
The oral suspension must be shaken 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.
The weight of animal should be accurately determined before treatment.

12. WITHDRAWAL PERIOD

Meat and offal: 73 days

13. 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 after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 6 months.

14. SPECIAL WARNING(S)

Special warnings for each target species:
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It is recommended to treat all piglets in a litter.

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Special precautions for use in animals:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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Avoid skin and eye contact with the product.
In case of accidental exposure, wash any splashes from skin or eyes immediately with water.

Wash hands and exposed skin after use.
Do not eat, drink or smoke whilst using the product.

Interaction with other medicinal products and other forms of interaction:
None known.
There is no interaction in combination with iron supplementation

Overdose (symptoms, emergency procedures, antidotes):
No signs of intolerance were observed in piglets up to threefold overdose.

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

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17. OTHER INFORMATION

Package sizes:
Bottle of 1 L
Cardboard box with 1 bottle of 250 ml

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EXP
Batch
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To be supplied only on veterinary prescription.
Keep out of the sight and reach of children.

Approved 29 January 2021