ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) responsible for batch release

Ceva Santé Animale
10 avenue de la Ballastière
33500 Libourne
France

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substances in Forceris are allowed substances as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmacologically active substances	Marker residue	Animal species	MRLs (µg/kg)	Target tissues	Other provisions	Therapeutic classification
Toltrazuril	Toltrazuril sulfone	All mammalian food producing species	100 150 500 250	Muscle Fat Liver Kidney	For porcine species the fat MRL relates to 'skin and fat in natural proportions'. Not for use in animals from which milk is produced for human consumption. Not for use in animals from which eggs are produced for human consumption.	Antiparasitic agents/ Agents acting against protozoa
		Poultry	100 200 600 400	Muscle Skin and fat Liver Kidney		
Iron (as gleptoferron)	The "No MRL required" classification for iron dextran and iron glucoheptonate is considered to apply to gleptoferron as gleptoferron is expected to release iron dextran and iron glucoheptonate.					

The excipients listed in section 6.1 of the SPC are either allowed substances for which

table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

OUTER CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forceris 30 mg/ml + 133 mg/ml suspension for injection for piglets
toltrazuril / iron (III) (as gleptoferron)

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 30 mg toltrazuril and 133 mg iron (III) (as gleptoferron)

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml
250 ml
500 ml

5. TARGET SPECIES

Pigs (piglets 24 to 96 hours after birth)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.

Shake well (for 20 seconds) before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 70 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 28 days.

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC 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.

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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/5007

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forceris 30 mg/ml + 133 mg/ml suspension for injection for piglets
toltrazuril / iron (III) (as gleptoferron)

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 30 mg toltrazuril and 133 mg iron (III) (as gleptoferron)

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml
250 ml
500 ml

5. TARGET SPECIES

Pigs (piglets 24 to 96 hours after birth)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.

Shake well (for 20 seconds) before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 70 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 28 days.

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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/5007

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Forceris 30 mg/ml + 133 mg/ml suspension for injection for piglets

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

Marketing authorisation holder and manufacturer responsible for batch release:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forceris 30 mg/ml + 133 mg/ml suspension for injection for piglets
toltrazuril / iron (III) (as gleptoferron)

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

Each ml contains:

Active substances:

Toltrazuril	30.0 mg
Iron (III)	133.4 mg
(as gleptoferron)	355.2 mg

Excipients:

Phenol	6.4 mg

Dark brown suspension.

4. INDICATION

For the concomitant prevention of iron deficiency anaemia and prevention of clinical signs of coccidiosis (diarrhoea) as well as reduction in oocyst excretion, in piglets in farms with a confirmed history of coccidiosis caused by *Cystoisospora suis.*

5. CONTRAINDICATIONS

Do not use in piglets suspected to be suffering from a deficiency of vitamin E and/or selenium.

6. ADVERSE REACTIONS

Deaths have been reported very rarely in piglets following the administration of parenteral iron injections. These deaths have been associated with genetic factors or deficiencies of vitamin E and/or selenium.
Piglet deaths have been reported which have been attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendothelial system.

Hypersensitivity reactions can occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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.

7. TARGET SPECIES

Pigs (piglets 24 to 96 hours after birth)

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

Intramuscular use.

Shake well (for 20 seconds) before use.

The recommended dose is 45 mg of toltrazuril and 200 mg of iron per piglet, that is, 1.5 ml of Forceris suspension per piglet, to be administered once, in a single intramuscular injection behind the ear, between 24 and 96 hours after birth.

For the 100 ml vials, the rubber stopper may be punctured up to 30 times. For the 250 ml and 500 ml vials, the rubber stopper may be punctured up to 20 times. If more injections than that are needed, the use of a multiple-dose syringe is recommended.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Meat and offal: 70 days.

11. SPECIAL STORAGE CONDITIONS

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

Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:
As with any antiparasiticide, frequent and repeated use of antiprotozoals from the same class may lead to the development of resistance.
It is recommended to administer the product to all the piglets in a litter.
Once clinical signs of coccidiosis are evident, damage to the small intestine will have already occurred. Therefore, the product should be administered to all animals before the expected onset of clinical signs, that is, in the prepatent period.
Hygienic measures may reduce the risk of porcine coccidiosis. It is therefore recommended to concomitantly improve the hygiene conditions in the farm concerned, particularly by increasing dryness and cleanliness.
The product is recommended in piglets weighing between 0.9 and 3 kg.

Special precautions for use in animals:
The recommended dose should not be exceeded, given the relatively low margin of safety for the veterinary medicinal product. The product must not be administered more than once.

It is not recommended to use the veterinary medicinal product in piglets weighing less than 0.9 kg.
Only use this veterinary medicinal product where *Cystoisospora suis* has been historically confirmed on a farm. The responsible veterinarian should take into account the results of clinical examinations and/or analysis of faecal samples and/or histological findings which confirmed the presence of *C. suis* in a previous infection episode on the farm.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to iron (as gleptoferron complex) or toltrazuril or any of the excipients should avoid contact with the veterinary medicinal product.

Exposure to the veterinary medicinal product may cause eye irritation or adverse effects to the skin. Avoid skin and eye contact with the product. In case of accidental exposure to the skin or eyes, wash the affected area with water.

Accidental self-injection may cause local reactions such as irritation, granulomas, or severe anaphylactic reactions in sensitive people. Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

This product may be harmful for the unborn child. Pregnant women and women intending to conceive should avoid contact with the veterinary medicinal product, especially accidental self-injection.

Wash hands after use.

Pregnancy and lactation:
Not applicable.

Interactions with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes), if necessary:
In safety studies, after any overdosage, an increased susceptibility for (systemic) bacterial disease, arthritis, and abscess formation was observed and a dose-dependent increase in mortality could not be excluded.
During overdosage studies, a transient reduced erythrocyte count, haematocrit and hemoglobin concentration without clinical signs was observed after day 14 following single administration in the target animal safety studies at three times the highest recommended dose (mean 261 mg/piglet toltrazuril and 1156 mg/piglet iron). At 3 times the recommended dose (135 mg/piglet toltrazuril and 600 mg/piglet iron) only a slight transient reduced erythrocyte count was observed after 21 days.
Doses higher than 150 mg/kg/day and 667 mg/kg/day for toltrazuril and iron respectively, *i.e.* 3 times the highest recommended dose, have not been evaluated in the target animal safety studies. The tolerance of the product after repeated administrations has not been assessed.

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 MATERIAL, 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.

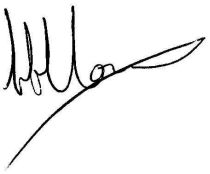
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

Pack sizes:
Box with 1 vial of 100 ml.
Box with 1 vial of 250 ml.
Box with 1 vial of 500 ml.

Not all pack sizes may be marketed.



Approved 11 October 2022