ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Phenol	6.4 mg
Sodium chloride	
Docusate sodium	
Simethicone emulsion	
Silica, colloidal anhydrous	
Povidone	
Water for injections	

Dark brown suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (piglets 24 to 96 hours after birth)

3.2 Indications for use for each target species

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.*

3.3 Contraindications

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

3.4 Special warnings

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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product is recommended in piglets weighing between 0.9 and 3 kg.

3.5 Special precautions for use

Special precautions for safe use in the target species:
The recommended dose should not be exceeded, given the relatively low margin of safety for the veterinary medicinal product. The veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs (piglets):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction Death[1]

[1] Following the administration of parenteral iron injections, associated with genetic factors or deficiencies of vitamin e and/or selenium or attributed to increased susceptibility to infection due to temporary blocking of the reticuloendothelial system.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramuscular use.

Shake well before use for a minimum of 20 seconds.

The recommended dose is 45 mg of toltrazuril and 200 mg of iron per piglet, that is, 1.5 ml of the veterinary medicinal product 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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 haemoglobin 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 veterinary medicinal product after repeated administrations has not been assessed.

3.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 70 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP51BC01

4.2 Pharmacodynamics

Toltrazuril is a triazinon derivative and an antiprotozoal agent. It has coccidiocidal activity against all intracellular development stages of the genera *Cystoisospora*, that is, merogony (asexual multiplication) and gamogony (sexual phase).

Iron is an essential micronutrient. It plays a major role in the transport of oxygen via haemoglobin and myoglobin, as well as having a key role in enzymes, such as cytochromes, catalases, and peroxidases. Injectable iron-carbohydrate complexes, such as gleptoferron, are established haematinic agents in veterinary medicine and are effective in significantly increasing the haemoglobin levels in piglets raised under intensive farming conditions in which an all milk diet for several weeks does not provide an adequate source of iron. Following intramuscular injection, gleptoferron is absorbed and metabolised to release the iron for use and/or storage in accordance with the nutritional status of the animal. Excess iron is stored principally in the liver.

4.3 Pharmacokinetics

After intramuscular administration of 1.5 ml/piglet of Forceris, maximal concentrations of 7 mg/l of toltrazuril were reached about 6 days after administration (T_{max} ranging from 4 to 7 days), and the AUC was about 57 day.mg/l.

Toltrazuril is primarily metabolised into toltrazuril sulfone. After intramuscular administration of 1.5 ml/piglet of Forceris the maximal concentration of 10 mg/l for toltrazuril sulfone was reached about 13 days after administration (T_{max} ranging from 10 to 19 days), and the AUC was about 183 day.mg/l.

Toltrazuril and toltrazuril sulfone were eliminated slowly with a half-life of 3 days each. The principal route of excretion is via the faeces.

After intramuscular injection of 1.5 ml/piglet of Forceris, iron is absorbed rapidly from the injection site into the capillaries and the lymphatic system and a maximal concentration of 645 mcg/ml was reached after approximately 0.5 day, the AUC was about 699 day.mcg/ml. Since iron is recycled in the body little of the absorbed iron is excreted. Very small losses occur in the faeces, sweat and urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Translucent multi-layered plastic (polypropylene/ethylene vinyl alcohol/polypropylene) vials with bromobutyl rubber stoppers coated with a fluor film or chlorobutyl rubber stoppers and aluminium and plastic flip capsules, containing 100 ml, 250 ml or 500 ml suspension for injection.

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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/235/001–003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 23/04/2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

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

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

100 ml
250 ml
500 ml

4. TARGET SPECIES

Pigs (piglets 24 to 96 hours after birth)

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular use.
Shake well before use for a minimum of 20 seconds.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 70 days.

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

14. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/235/001 (100 ml)
EU/2/19/235/002 (250 ml)
EU/2/19/235/003 (500 ml)

15. 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

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. TARGET SPECIES

Pigs (piglets 24 to 96 hours after birth)

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Shake well before use for a minimum of 20 seconds.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 70 days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

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.

3. Target species

Pigs (piglets 24 to 96 hours after birth)

4. Indications for use

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. Special warnings

Special warnings:
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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product is recommended in piglets weighing between 0.9 and 3 kg.

Special precautions for safe use in the target species:
The recommended dose should not be exceeded, given the relatively low margin of safety for the veterinary medicinal product. The veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

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

Overdose:
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 haemoglobin 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 veterinary medicinal product after repeated administrations has not been assessed.

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

7. Adverse events

Pigs (piglets 24 to 96 hours after birth):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hypersensitivity reaction, Death[1]

[1] Following the administration of parenteral iron injections, associated with genetic factors or deficiencies of vitamin E and/or selenium or attributed to increased susceptibility to infection due to temporary blocking of the reticuloendothelial system.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Intramuscular use.

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

9. Advice on correct administration

Shake well before use for a minimum of 20 seconds.
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.

10. Withdrawal periods

Meat and offal: 70 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 carton and the vial label after "Exp". The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/19/235/001: Cardboard box with 1 vial of 100 ml
EU/2/19/235/002: Cardboard box with 1 vial of 250 ml
EU/2/19/235/003: Cardboard box with 1 vial of 500 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

06/2025

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Ceva Santé Animale
8 rue de Logrono
33500 Libourne
France
Tel: +800 35 22 11 51
E-mail: pharmacovigilance@ceva.com

Manufacturer responsible for batch release
Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
France