# 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:**

| | |
|---|---|
| Phenol | 6.4 mg |

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Suspension for injection.
Dark brown suspension.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Pigs (piglets 24 to 96 hours after birth)

### 4.2 Indications for use, specifying the 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.*

### 4.3 Contraindications

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

### 4.4 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.

## 4.5 Special precautions for use

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.

## 4.6 Adverse reactions (frequency and seriousness)

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).

## 4.7 Use during pregnancy or lactation

Not applicable.

## 4.8 Interaction with other medicinal products and other forms of interaction

None known.

## 4.9 Amounts to be administered and administration route

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.

## 4.10 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.

## 4.11 Withdrawal period(s)

Meat and offal: 70 days.

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Toltrazuril, combinations
ATCvet code: QP51AJ51

### 5.1 Pharmacodynamic properties

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.

### 5.2 Pharmacokinetic particulars

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 µg/ml was reached after approximately 0.5 day, the AUC was about 699 day.µg/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.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Phenol
Sodium chloride
Docusate sodium
Simethicone emulsion
Silica, colloidal anhydrous
Povidone

Water for injections

### 6.2 Major incompatibilities

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

### 6.3 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.

### 6.4 Special precautions for storage

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

### 6.5 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 stoppers and aluminium and plastic flip capsules, containing 100 ml, 250 ml or 500 ml.

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.

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

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

## 7. MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
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Wooburn Green
High Wycombe
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## 8. MARKETING AUTHORISATION NUMBER

Vm 15052/5007

## 9. DATE OF FIRST AUTHORISATION

23 April 2019

## 10. DATE OF REVISION OF THE TEXT

May 2024

Approved: 13 May 2024