

# FORCERIS®

## COMPOSITION

|                                |          |
|--------------------------------|----------|
| Toltrazuril .....              | 30.0 mg  |
| Iron(III) .....                | 133.4 mg |
| (as Glepoferron) .....         | 355.2 mg |
| Excipients q.s. ....           | 1.0 mL   |
| Phenol (As preservative) ..... | 6.4 mg   |

## 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 glepoferron, 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, glepoferron 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.

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), 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.

## PHARMACODYNAMICS

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## PHARMACOKINETICS

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## TARGET SPECIES AND INDICATIONS

FORCERIS® is indicated for Pigs (piglets 1-3 days old) for the concomitant prevention of iron deficiency anaemia and prevention of clinical signs of coccidiosis (diarrhoea) as well as reduction in oocyst excretion, in farms with a confirmed history of coccidiosis caused by *Cystoisospora* suis.

## DOSAGE AND ADMINISTRATION

**Piglets:** 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 1 and 3 days of age (i.e. 24 to 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.

## CONTRAINDICATION

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

## WITHDRAWAL PERIOD

### Piglets:

Meat and offal: 70 days.

## WARNINGS AND PRECAUTIONS

### 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

#### 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.

## OVERDOSE AND TREATMENT

In safety studies, after any overdose, 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 overdose 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.

**Environmental properties:** Not Applicable.

### Adverse effects/undesirable effects:

Deaths have been reported very rarely in piglets following the administration of iron parenteral 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).

**Usage during pregnancy and lactation:** Not Applicable.

**Interaction with other medicaments:** None known.

## PACK SIZES

Box with 1 vial of 100ml. Box with 1 vial of 250ml. Box with 1 vial of 500ml

Not all pack sizes may be marketed.

## STORAGE

Store at temperature below 30°C.

Once broached, it can be used within 28 days, if kept at temperature below 30°C.

Any unused product or waste materials should be disposed in accordance with national requirements.

Date of Revision of Package Insert: 26/06/2020

**Registered by:** Ceva Animal Health Malaysia Sdn. Bhd.

27-2, Oval Damansara, No. 685, Jalan Damansara 6000 Kuala Lumpur

**Mfd. By:** Ceva Santé Animale

10 Avenue de la Ballastière

33500 Libourne, France

Controlled Medicine  
**TO BE PRESCRIBED AND TREATED WITH BY  
REGISTERED VETERINARY SURGEONS ONLY  
FOR VETERINARY USE ONLY**  
Keep out of reach of children  
**Jauhkan ubat daripada kanak-kanak**

| LABEL CODE:                                                                                                                                    | VERSION:                         | COLORS:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            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| <b>5LFORCE3-100</b><br>PRODUCT: FORCERIS SUSPENSION<br>FOR INJECTION<br>PACK SIZE: 100, 250, 500 ML<br>COUNTRY: MY<br>DIMENSIONS: 200 x 160 mm | VERSION: 1<br><br>MMM/YY: JAN 22 | Black<br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br> |