SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZincoTec Zinc Oxide 1000 mg/g Premix for Medicated Feeding Stuff

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition	Quantitative composition
Zinc Oxide (Equivalent to zinc 803.4 mg/g)	1000.0 mg/g

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

A soft, white or yellowish dry, amorphous powder.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs up to 10 weeks of age.

4.2 Indications for use, specifying the target species

For the treatment and control of diarrhoea in young pigs

4.3 Contraindications

None known

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in animals

Feeding of high zinc concentrations may stimulate the occurrence of resistance to zinc in the pig gut microflora and may play a role in the co-selection of methicillin-resistant *Staphylococcus aureus* (MRSA) and in increasing the proportion of multiresistant *Escherichia coli*.

ii. Special precautions for the person administering the veterinary medicinal product to animals.

Use in a well ventilated area, Avoid inhalation of the product while preparing the

medicated feed.

Wear either a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN143 when mixing or handling the feed.

Avoid contact with the eyes by wearing protective goggles or safety glasses. In case of accidental eye contact irrigate thoroughly with large quantities of water. Avoid contact with the skin by wearing protective clothing, including impermeable gloves. In case of accidental skin contact, wash the exposed skin with soap and water.

Contaminated clothing should be removed and washed before being reused. In case of accidental ingestion, drink plenty of water and seek medical attention.

Wash hands after use.

iii Other precautions regarding impact on the environment

Zinc is potentially toxic to aquatic organisms, and can affect growth, survival and reproduction in both aquatic and terrestrial plants and animals. Zinc is also persistent in soils and may accumulate in sediments. Toxicity will depend on environmental conditions and habitat types.

The risk to the environment can be reduced by adhering to the following measures.

When spreading manure from treated animals, the maximum total zinc load as defined in the national or local regulations must be strictly respected. Undiluted manure from treated piglets should not be applied to land. Dilution with manure from untreated animals or sows is required so that the total amount of treated piglet manure is as low as possible and never exceeds 40% (the ratio when manure of weaned piglets and sows is stored together). The product should not be used on farms where mixing of manure from treated animals with manure of non-treated animals is not possible.

Manure containing zinc should not be spread on the same area of land in successive years to avoid accumulation of zinc, which may cause adverse effects in the environment. When spreading manure from treated animals, the minimum distance to surface water, as defined in the national or local regulations, has to be strictly respected, and at least a minimum buffer zone of 3 m applied, because the manure contains zinc which may cause adverse effects in the aquatic environment.

The bioavailability of zinc, and therefore the environmental risk, varies between soil types. It is recommended that the zinc content of soil and surface water outside of the minimum buffer zone of 3m is monitored to ensure that the maximum total zinc load as defined in the national or local regulations is strictly respected.

4.6 Adverse reactions (frequency and seriousness)

The administration of the medicated premix may lead to a white-yellowish colouring in faeces, which stops following the withdrawal of treatment.

With prolonged use copper deficiency is possible associated with hypochromic anaemia. Furthermore, growth depression, decreased food consumption and joint pain are described.

The administration of the medicated premix may alter certain biological parameters (alkaline phosphatase, α-amylase activity), which reverts following withdrawal of the treatment

4.7 Use during pregnancy, lactation or lay

Not applicable

4.8 Interaction with other medicinal products and other forms of interaction

Factors affecting the oral bioavailability of zinc include the presence of minerals in the diet that compete for transport (Fe, Cu) and interfering substances that may bind zinc (phytate-Ca). High zinc dosages may also affect the availability of minerals such as Fe and Cu.

4.9 Amount(s) to be administered and administration route

For oral administration only

For incorporation into dry feed at a registered/licensed mill. For more information:

- In the UK refer to Veterinary Medicines Guidance - Retail of Veterinary Medicines
- In Ireland seek advice from the Department of Agriculture, Food and the Marine

Dosage: 100mg zinc oxide/kg bodyweight continuously for up to 14 days.

Administer 2900-3100 mg/kg ZincoTec (which provides 2320 - 2489 mg/kg elemental zinc) so that the amount of zinc already present in the feed (naturally occurring zinc plus added nutritional zinc) is taken account of to ensure that the final feed contains 2500 mg/kg of elemental zinc.

To ensure adequate distribution of the product in the final feed it is recommended that it be premixed with a suitable quantity of feed ingredients before blending into the final feed. The final feed should be fed continuously as the only feed for up to 14 days.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No known problems.

4.11 Withdrawal period(s)

Animals must not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption only after 28 days from the end of treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Anti-diarrhoeal
ATC Vet Code: **QA07XA91**

5.1 Pharmacodynamic properties

The mode of action of zinc oxide in the treatment and control of diarrhoea in pigs has not been determined. It has been shown to have a favourable effect on the gut microflora by helping to prevent the reduction in diversity of microflora that occured in the intestines of control pigs during the second week after weaning.

5.2 Pharmacokinetic properties

Absorption – Zinc is an essential trace element for livestock required for the maintenance of daily bodily function. Zinc oxide is known to be relatively poorly absorbed and therapeutic levels have increased blood levels by a factor of two only.

Distribution – Therapeutic levels of zinc oxide fed for four weeks after weaning have been shown to increase zinc levels in the liver and kidney of pigs by a factor of approximately five and two respectively. No increases in muscle levels were noted.

Biotransformation – Zinc is a trace element essential for daily metabolism in the body. Since therapeutic levels are poorly absorbed, it is believed that most is voided unchanged in the faeces.

Elimination – Most zinc from zinc oxide is excreted in the faeces without absorption. A small proportion is excreted via the kidneys in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

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: 2 Years.

Shelf-life after first opening of the immediate packaging: 6 months.

Shelf life after incorporation into meal or pelleted feed: 3 Months

6.4 Special precautions for storage

- Store in a clean dry place. Do not store above 25°C
- Store in tightly closed original container.
- Store away from food, drink and animal feedingstuffs
- Close the bag securely after use.

6.5 Nature and composition of immediate packaging

Three-ply paper sacks containing 25kg of a soft, white or yellowish white amorphous powder.

Sacks are filled via a side valve, which is tucked in and glued to form a closure.

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

Potentially dangerous to fish and aquatic life. Do not contaminate surface waters or ditches with the product or used containers.

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

SCA NuTec (Provimi Ltd)
NuTec Mill
Eastern Avenue
Lichfield
Staffordshire
WS13 7SE

8. MARKETING AUTHORISATION NUMBER

Vm 03941/4000

9. DATE OF FIRST AUTHORISATION

09 July 1990

10. DATE OF REVISION OF THE TEXT

November 2018

Approved 01 November 2018