ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Three ply paper sacks containing 25 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Zinc oxide 1000.0 mg/g
(corresponding to zinc 803.4 mg)

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4. PACKAGE SIZE

25 kg

5. TARGET SPECIES

Pigs up to 10 weeks of age

6. INDICATION(S)

7. CONTRAINDICATIONS

None known.

8. ADVERSE REACTIONS

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

9. METHOD AND ROUTE(S) OF ADMINISTRATION

Orally via medicated feedingstuff

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.

10. 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.

11. SPECIAL WARNING(S), IF NECESSARY

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*.

Precautions for Users:
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 EN 143 when mixing or handling the feed.

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.

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.

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

Environmental Precautions

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.

Overdose (symptoms, emergency procedures, antidotes)

No known problems.

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.

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

12. EXPIRY DATE

EXP {month/year}

Once opened use within 6 months.

13. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C
Store in the original package
Keep the container tightly closed

14. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of unused product and waste materials in accordance with local requirements.

ZincoTec Zinc Oxide 1000.0 mg/g Premix for medicated Feedingstuff should not enter water courses as this may be dangerous for fish and other aquatic organisms.

15. 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.

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

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

Keep out of the sight and reach of children.

17. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

18. MARKETING AUTHORISATION NUMBER(S)

Vm 03941/4000

19. MANUFACTURER'S BATCH NUMBER

Batch{number}

Approved 01 November 2018