SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gutal 1000 mg/g premix for medicated feeding stuff for piglets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g contains:

Active substance:
Zinc oxide 1000.0 mg (Corresponding to zinc 803.4 mg)

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.
A soft, white or yellowish, dry, amorphous powder.

4. CLINICAL PARTICULARS

4.1 Target species

Piglet (weaned piglets)

4.2 Indications for use, specifying the target species

For the prevention of post-weaning diarrhoea.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Studies have shown zinc oxide to be beneficial in piglets at risk of developing mild to moderate diarrhoea. However, there are no studies available in piglets at risk of developing severe/haemorrhagic forms of diarrhoea.

4.5 Special precautions for use

Special precautions for use in animals

The product should only be administered to animals at risk of diarrhoea, for example if the piglets are from sows with a history of regularly occurring cases of post-weaning diarrhoea.
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 coselection of MRSA and in increasing the proportion of multiresistant E.coli.

Special precautions to be taken by 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 EN 143 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.

Other precautions regarding impact on the environment

Zinc is very toxic to aquatic organisms, but can affect growth, survival and reproduction in both aquatic and terrestrial plants and animals. Zinc is 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 has to be strictly respected. Undiluted manure from treated piglets should not be applied to land. Dilution with manure of untreated animals or sows is required so that the total amount of treated piglet manure is as low as possible and is never exceeding 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.

The bioavailability of zinc, and therefore the environmental risk, varies between soil types. Manure from treated piglets should not be spread on vulnerable soil types, which have been identified as freely draining, acidic (pH ≤6), sandy soils.

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.

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 anemia. 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 Amounts to be administered and administration route

Oral use only.
For incorporation into dry feed at a registered/licensed feed mill.
Administer 2900 - 3100 mg of the product per kg of dry feed (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. Medicated feed may be pelleted using a pre-conditioning step for 5 minutes at a temperature not exceeding 85°C.The final feed should be fed as the only feed for 14 days from weaning.

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

Not known

4.11 Withdrawal period(s)

Meat and offal: 28 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ANTIDIARRHEALS, INTESTINAL ANTI-INFLAMMATORY - Other antidiarrheals

ATC Vet Code QA07XA91.

5.1 Pharmacodynamic properties

The mode of action of zinc oxide in the prevention of diarrhoea has not been fully established, but may involve improvement of gastrointestinal barrier function. In

addition, changes in the intestinal microflora of weaned piglets after administration of high levels of zinc oxide have been observed.
Resistance to zinc is conferred by bacterial cation efflux channel-tunnels, e.g. CzrC. Zinc resistance genes can be located on the same mobile genetic elements as antibiotic resistance genes, e.g. staphylococcal cassette chromosome mec, which also contains the mecA gene coding for methicillin resistance. The proportion of multi-resistant E. coli may be increased in piglets feeding high dose ZnO.

5.2 Pharmacokinetic particulars

Absorption – Zinc oxide is known to be relatively poorly absorbed and therapeutic levels have increased blood levels by a factor of only two.

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 factors of approximately five and two, respectively. No increase in muscle levels was noted.

Biotransformation – Since zinc oxide at therapeutic levels is 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 in the urine.

5.3. Environmental properties

Zinc is very toxic to aquatic organisms and is persistent in soils and sediments.
Zinc may accumulate in soil following continual application of manure from treated animals; with acidic sandy soils being most vulnerable.
The bioavailability of zinc, and therefore the environmental risk, varies between soil types and environmental conditions (e.g. dissolved organic carbon, calcium and pH).

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

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

6.5 Nature and composition of immediate packaging

Package sizes:
Bag of 5 kg
Bag of 20 kg

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

EXTREMELY 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

Huvepharma NV
Uitbreidingstraat 80
2600 Anwerp
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 30282/4021

9. DATE OF FIRST AUTHORISATION

15 December 2015

10 DATE OF REVISION OF THE TEXT

September 2019

PROHIBITION OF SALE, SUPPLY AND/OR USE

For Spain (ES):

For animal treatment only. To be supplied only on veterinary prescription.

Approved: 20 September 2019