

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bags of 5 kg and 20 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gutal 1000 mg/g premix for medicated feeding stuff for piglets.
Zinc oxide

2. STATEMENT OF ACTIVE SUBSTANCES

Zinc Oxide 1000 mg/g

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.

4. PACKAGE SIZE

5 kg
20 kg

5. TARGET SPECIES

Piglet (weaned piglets)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For incorporation into dry feed at the registered mill.
Oral use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 28 days.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings

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.

10. EXPIRY DATE

EXP {month/year}

Once broached, use by.....

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

Shelf life of the veterinary medicinal product after incorporation into meal or pelleted feed: 3 months.

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

13. 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.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 30282/4021

17. MANUFACTURER'S BATCH NUMBER
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Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

Manufacturer responsible for batch release:

Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Zinc oxide 1000 mg/g
A soft, white or yellowish, dry, amorphous powder.

4. INDICATION(S)

For the prevention of post-weaning diarrhoea.

5. CONTRAINDICATIONS

None known.

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

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

7. TARGET SPECIES

Piglet (weaned piglets)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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. The final feed should be fed as the only feed for 14 days from weaning.

Medicated feed may be pelleted using a pre-conditioning step for 5 minutes at a temperature not exceeding 85°C.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

Meat and offal: 28 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in the original package

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP

The expiry date refers to the last day of that month.

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

Shelf life after incorporation into meal or pelleted feed: 3 months.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

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. 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 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 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.

Use during pregnancy, lactation or lay:

Not applicable.

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

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

Not known.

Incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:

Bag of 5 kg

Bag of 20 kg.

Not all pack sizes may be marketed

Approved: 20 September 2019

